Feasibility and Preliminary Outcomes from a Pilot Study of a Brief Psychological Intervention for Families of Children Newly Diagnosed with Cancer

Anne E. Kazak,1,2 PhD, ABPP, Steven Simms,1 PhD, Melissa A. Alderfer,1,2 PhD, Mary T. Rourke,1 PhD, Terry Crump,1 PhD, Kelly McClure,1 PhD, Portia Jones,1 BA, Alyssa Rodriguez,1 PhD, Alexandra Boeving,1 PhD, Wei-Ting Hwang,2 PhD, and Anne Reilly,1,2 MD

1The Children's Hospital of Philadelphia and 2The University of Pennsylvania

Objective To report initial feasibility and outcome from a pilot study of a new three-session intervention for caregivers of children newly diagnosed with cancer, Surviving Cancer Competently Intervention Program—Newly Diagnosed (SCCIP-ND). Method Nineteen families (38 caregivers) were randomly assigned to SCCIP-ND or treatment as usual subsequent to learning of their child’s illness. The study design included pre- and 2-month postintervention assessments, with state anxiety and posttraumatic stress symptoms as outcomes. Feasibility was based on therapist feedback and supervision, program evaluations, and data from study-tracking procedures. Results SCCIP-ND appears to be an acceptable intervention that can be used successfully with caregivers over the first few months after diagnosis. Recruitment and retention data document feasibility but also highlight challenges. Preliminary outcome data show changes in the desired direction [e.g., reduced anxiety and parental posttraumatic stress symptoms (PTSS)]. Conclusions The pilot data are supportive of the value and challenges of developing evidence-based family interventions in pediatric psychology.

Key words cancer; children; families; intervention; posttraumatic stress; randomized clinical trial.

Psychosocial support for children with cancer and their families is widely recommended to assist families with short and longer-term adjustment to the changes prompted by their child’s illness (American Academy of Pediatrics, 1997; Noll & Kazak, 2004). Nevertheless, little is actually known about what types of care are provided, their frequency, or outcomes, even across major pediatric oncology centers. Although there is growing empirical support for interventions for mothers of children with cancer (Sahler et al., 2002; Streisand, Rodrique, Houck, Graham-Pole, & Berlant, 2000), there are no evidence-based interventions that include multiple members of the family during active cancer treatment. This gap is striking given the relatively large literature on family adjustment to pediatric illness generally (Kazak, Rourke, & Crump, 2003) and clinical models for using family systems approaches (Kazak, Simms, & Rourke, 2002). The development of a practical and evidence-based family intervention to reduce or prevent short and longer-term distress in childhood cancer is an overarching goal of the pilot work described in this study.

Several factors have converged recently to facilitate intervention research in pediatric oncology. First, substantive improvements in survival rates for children with cancer have contributed to an infusion of enthusiasm and support for research in cancer survivorship, with
psychological outcomes for patients and families central among the documented and emerging “late effects” of treatment (Friedman & Meadows, 2002). Second, current economic constraints in healthcare have the potential to jeopardize psychosocial services that may be viewed as expensive and labor intensive, highlighting the importance of establishing the evidence base for psychological interventions that help children, both directly and indirectly. Third, there is a gestalt favorable towards intervention studies in general, with appreciation that intervention approaches and targets cut across the child’s social ecological context.

There are, however, challenges entailed in conducting family interventions in pediatric psychology. Concerns about the complexity of working with families and implicit suggestions that families are difficult to recruit and retain in intervention studies may have deterred the development of family interventions. In addition, generic family psychoeducational approaches have not shown differences over time between treatment and control groups (Hoekstra-Weebers, Heuvel, Jaspers, Kamps, & Klip, 1998). These data highlight the importance of interventions that are carefully timed and closely focused on specific malleable outcomes, as opposed to a more general emphasis on adjustment (Kazak, 2005).

One empirically supported model that may guide the development of family interventions is posttraumatic stress. Parental posttraumatic stress symptoms (PTSS) have been reported from multiple studies and laboratories (Brown, Madan-Swain, & Lambert, 2003; Kazak et al., 1997; Kazak et al., 2004; Manne, DuHamel, Gallelli, Sorgen, & Redd, 1998; Manne et al., 2002). An intervention for adolescent survivors who have completed cancer treatment and their families, the Surviving Cancer Competently Intervention Program (SCCIP, Kazak et al., 1999), has been developed and tested in a randomized clinical trial of 150 families. Family members identify ongoing distressing memories, use cognitive behavioral approaches to help reduce their impact, and process their beliefs with others in their families and with other families in a 1-day intervention that includes four embedded sessions. The results indicate that fathers and survivors in the treatment arm showed significant declines in PTSS relative to those in a waitlist control group (Kazak et al., in press).

Although the natural course of family adjustment across the first year postdiagnosis is one of improvement (Sawyer, Antonioue, Toogood, Rice, & Baghurst, 1993; Steele, Long, Reddy, Luhr, & Phipps, 2003), family adjustment at and just after diagnosis is predictive of long-term adaptation (Best, Streisand, Catania, & Kazak, 2002; Kazak & Barakat, 1997; Kupst & Schulman, 1988; Kupst et al., 1995). The many traumatic aspects of cancer treatment that parents face at diagnosis and during early treatment (e.g., learning one’s child has cancer, seeing your child in pain, concern that your child could die, intensive care admissions, and emergency room visits) may challenge positive adaptation. To address the needs of families at this critical time and to provide an intervention that may promote optimal long-term adjustment, the researchers developed and piloted a new three-session intervention called Surviving Cancer Competently Intervention Program—Newly Diagnosed (SCCIP-ND), extending the SCCIP treatment model to beliefs of parents/caregivers at diagnosis.

The purposes of this article are twofold. First, given that this is a new and innovative intervention, the researchers describe it briefly to illustrate the goals and process of a family intervention in pediatric psychology. Second, in light of the importance of assessing feasibility in applied-intervention research the researchers identified four topics and a related series of questions by which feasibility may be evaluated: (1) Acceptability. Were we able to implement the intervention? Did it seem clinically relevant and doable, and what, if any significant clinical concerns came up? Was the treatment generally acceptable to participants? (2) Recruitment and Retention. Did we recruit a representative sample? What was the participation rate? Did the randomization work? What was the attrition? What can be said about dropouts? (3). Timeline. Were we able to conduct the intervention as planned shortly after diagnosis? (4) Preliminary Outcomes. Within the context of a small pilot study, what evidence is there for the likely effect of the intervention on primary outcomes?

Method

Intervention Design

This was a pilot randomized clinical trial (RCT) of a new three-session intervention for parents/caregivers of newly diagnosed pediatric oncology patients. Time 1 (T1, preintervention) data were collected from caregivers subsequent to their learning of their child’s cancer diagnosis. Families were randomized to the SCCIP-ND intervention or a control arm providing treatment as usual. Time 2 (T2, postintervention) data were collected 2 months after the final session and within a comparable period of time for the control group. The outcomes were PTSS and state anxiety.
Participants

Nineteen families, representing 38 parents/caregivers (20 female/18 male) participated. Nine families were randomized to the treatment arm and ten to the control group. There were no significant differences in disease or demographic variables between the two groups (Table I). Most families were married or partnered, with a range of income and educational attainment, and representation of ethnic minority families.

Procedure

Patients receiving a new diagnosis of a pediatric malignancy were identified through daily rounds. The family was provided with an initial verbal overview of the study by their primary oncologist or social worker and then approached about participating in this Institutional Review Board-approved study by a member of the research team. SCCIP-ND required that two parents/caregivers participate. Caregivers were defined by their relationship with the child. Therefore, in addition to couples, participant pairs could include extended family or friends who functioned in a caregiving role with the child. The researchers refer in this article to participants as primary and partner caregivers. Primary participants were those identified by the family as responsible for providing the largest amount of direct care for the child. In this study, all 19 primary caregivers were mothers. Of the

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<th>Table I. Demographics for Surviving Cancer Competently Intervention Program—Newly Diagnosed (SCCIP-ND) and Control Groups and Total Sample</th>
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<tr>
<td>Patient age (median in years)</td>
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<td>Diagnosis (N)</td>
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<td>Leukemia/lymphoma</td>
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<td>Primary caregiver educational level (N)</td>
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<td>African American</td>
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<td>Mixed race</td>
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<td>Psychosocial contact (median hours in first month)</td>
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<td>Child life</td>
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partner caregivers, 18 were fathers and one was a grandmother.

All participants provided written informed consent. Randomization used a predetermined concealed random assignment list maintained by a staff member unaware of patient identity. Self-report data from parents were collected by research assistants at T1 and T2.

The treatment arm consisted of three 45-min sessions of a manualized family intervention, SCCIP-ND. The goal was to deliver the intervention within the first month after the child’s cancer diagnosis. Sessions were scheduled at the convenience of families including evenings and weekends, and childcare was available. Two psychology fellows and one psychology graduate student were therapists. Each completed 18 hr of didactic and experiential training sessions and participated in weekly supervision throughout the study. Each session was audiotaped. Treatment fidelity was assessed independently by a treatment fidelity team using a manual developed in conjunction with the SCCIP-ND team.

Families randomized to the control condition received usual psychosocial care. Each family was assigned a social worker who attended the initial family meeting, provided resources and supplemental information about the diagnosis and treatment, and offered support. Social workers consulted with parents and the medical team on an ongoing basis to facilitate families’ adjustment. The services of child life specialists, including medical play and education, art and music therapies, and assistance with procedures were also provided to all families. Psychologists were available upon referral for child and family behavioral concerns. Usual psychosocial care was provided to all newly diagnosed families, irrespective of group assignment. We measured the amount and types of interactions families had with social work and child life within the first month of diagnosis to track the magnitude of services provided.

**Measures**

**Acute Stress Disorder Scale**

The Acute Stress Disorder Scale (ASDS) (Bryant, Moulds, & Guthrie, 2000) is a 19-item self-report inventory that assesses acute stress disorder. Each item is rated on a 5-point scale (1, not at all; 5, very much), yielding four symptom dimensions (dissociation, reexperiencing, avoidance, and arousal). Test–retest reliability for the total score \( r = 0.94 \) and subscales (0.87–0.96) were strong. The ASDS total score predicts subsequent posttraumatic stress on the Impact of Events Scale (Bryant et al., 2000). The ASDS was used at T1 for caregivers.

**Impact of Events Scale-Revised**

The Impact of Events Scale—Revised (IES-R; Weiss, & Marmar, 1997) is a 22-item self-report questionnaire that assesses PTSS associated with a specific event across three domains (intrusive thoughts, avoidance, hyperarousal). Items are rated on a weighted 4-point scale (0, not at all; 1, rarely; 3, sometimes; 5, often) for frequency of occurrence during the previous week. In studies of childhood cancer survivors internal consistency coefficients for the IES-R have ranged from 0.91 to 0.95 (Kazak et al. in press). The IES-R was administered at T2 to caregivers.

**State-Trait Anxiety Inventory**

The State-Trait Anxiety Inventory (STAI; Spielberger, 1983) is a 40-item self-report questionnaire assessing current and trait anxiety symptoms. The STAI is rated on a 4-point scale (1, not at all; 4, very much so). Test–retest reliability, internal consistency and construct and discriminative validity across gender and ethnic groups are strong. Caregiver state anxiety was measured at T1 and T2.

**Program Evaluation Form**

We created an 11-item form to be completed at the end of Session 3 asking participants their opinions about SCCIP-ND’s relevance, helpfulness, and format.

**Staff Activity forms**

Oncology social workers and child life specialists completed two analogous measures biweekly for each family in the study during the first month of participation, the Child Life Activity Form (CLAF) and the Social Work Activity Form (SWAF). Each form tracks the types and amounts of contact provided to the child and family. Data from the CLAF and SWAF were used to ascertain that usual psychosocial care had been provided.

**Intensity of Treatment Rating**

The Intensity of Treatment Rating (ITR) categorizes cancer treatment protocols into four groups by intensity (Hobbie et al., 2000). A pediatric oncologist, unaware of patient identity (AR), classified the treatment protocol for each patient.

**The Intervention**

Surviving Cancer Competently Intervention Program—Newly Diagnosed (SCCIP-ND) is an adaptation of an integrated cognitive behavioral and family therapy intervention developed and tested with adolescent survivors of childhood cancer and their families (SCCIP; Kazak et al., 1999; Kazak et al. in press). SCCIP-ND is intended...
for two caregivers of a child newly diagnosed with cancer. Caregivers work conjointly to identify beliefs about their experiences during the initial month of treatment, a time in which potentially traumatic events may occur. The focus is on understanding how beliefs about cancer and its treatment influence caregivers and to help family members anticipate the impact of cancer on the family over time. The SCCIP-ND manual was written by a multidisciplinary group. A draft of the manual was reviewed by a psychologist expert in pediatric traumatic stress who was not involved in the development process to provide feedback on its clarity and ease of use. In consultation with our treatment fidelity team a companion treatment fidelity protocol was also developed, necessitating minor revisions in the manual. The process of completing manual development took about 10 months.

Key Constructs
Four key constructs that cut across the sessions were identified: (1) Joining is the ongoing process by which a therapist relates to family members using acceptance, respect, curiosity, and honesty (ARCH; Micucci, 1998). (2) Maintaining an interpersonal focus assures that caregivers focus on how their effective coping helps their child’s adaptation. (3) Normalizing the family experience is helpful in decreasing feelings of isolation and anxiety. The emotional, behavioral, and interpersonal responses to cancer-related adversities are viewed as understandable responses to the trauma associated with diagnosis and treatment. (4) Focusing on the family’s strengths reflects the perspective that parents and families are competent, able to adapt to adverse circumstances, and to continue growing and developing as a family despite their child’s illness.

Multiple Family Video Discussion Group
Multiple Family Discussion Groups (MFDG), used in our prior SCCIP research, are established interventions that have been used in severe psychiatric disorders (McFarlane, 2002) and chronic child and adult illnesses (Gonzalez, Steinglass, & Reiss, 1989; Steinglass, 1998), including childhood cancer survivors (Ostroff & Steinglass, 1996). Although we believed that the presence of other families with similar experiences was important and therapeutic, the logistics of group intervention for families of newly diagnosed patients precluded a MFDG format. To preserve the opportunity for families to be exposed to other families, the researchers created a CD-ROM-based video group. In each session the therapist used a designated video clip of a group discussion among three families (3 mothers, 1 father) with a child in treatment for cancer. Parents in the video participated in a filmed 2-hr uncoached, guided discussion about the impact of cancer on the family. The tape was transcribed and the raw footage edited to create three 5-min clips for use in the three sessions. Each clip contained material relevant to that session to stimulate discussion.

Session 1. Identifying Beliefs About Cancer, its Treatment and the Impact on the Family
In Session 1, the therapist joins with the caregivers by first understanding and using the family’s style of relating to establish a collaborative relationship and reinforce the importance of the caregivers’ participation (i.e., potential benefits of the study). The therapist then provides a framework, the A-B-C Model (Ellis, 2001) for examining the relationship between adversities (diagnosis of pediatric cancer) and beliefs, and between beliefs and their emotional, behavioral, and relational consequences. Caregivers use the A-B-C Model to examine the relationships between their perceptions of cancer-related events and their feelings, actions, and relationships.

Session 2. Changing Beliefs to Enhance Family Functioning
This session is designed to address the process of changing one’s thoughts to produce different consequences for each participant and for the family. The therapist continues to join with the family and reaffirm the link between beliefs and relational consequences. For example, caregivers expand their discussion of the impact of cancer and their beliefs on familial and social relationships. Caregivers learn how to use reframing to modify their beliefs and subsequently, their emotional, behavioral, and interpersonal consequences. Participants are then coached to identify new beliefs that (a) accept the uncontrollable (e.g., “There is nothing we could have done to prevent our child’s illness.”); (b) focus on the controllable (e.g., “We can help our son cope with his procedures.”); (c) acknowledge their own strengths (e.g., “We are a strong family that can get through difficult times.”); and (d) use the positive (e.g., “My husband and I can support each other and respect the ways that we are different in coping with our daughter’s illness.”)

Session 3. Family Growth and the Future
By focusing on family growth in this session, the therapist helps caregivers consider the future, with cancer occupying an ever-present but diminishing role. The therapist uses two metaphors, “The Family Survival Roadmap” and “Putting Cancer in its Place,” to help caregivers recognize their beliefs about the family’s future, and share these beliefs with each other. The Family Survival Roadmap is a map (e.g., it has roads, bridges, potholes, overlooks, dead-ends) based on a tool our psychosocial team has
used successfully with families shortly after diagnosis. The map prompts caregivers to think about the course of their cancer journey and how they can begin the process of resuming a more normal developmental course in the future in light of the uncertainty imposed by the illness. The concept of “Putting Cancer in its Place” (Gonzalez et al., 1989) supports the incorporation of the disease into the family while diminishing its centrality. Caregivers discuss the personal significance of the metaphors, as well as how they can modify their beliefs, when necessary, to promote family growth. Finally, the therapist encourages caregivers to consider how they will incorporate what they have learned into their family life.

Results
The small sample precluded use of any inferential statistics and dictated only the most conservative interpretation of these data. Median scores were presented as measures of central tendency. Mean scores were used to compare sample scores with norms. Acceptability was described based on the experience of conducting SCCIP-ND and from supervisory sessions, treatment fidelity, and the program evaluation data. Recruitment and retention data and information about the timing of the intervention phases were based on data collected as part of the study-tracking procedures. Preliminary outcome data were derived from the STAI-State and ASDS at T1 and the STAI-state and the IES-R at T2 and are shown graphically. For PTSS, z-scores were used to transform the ASDS and IES-R scores, to provide a common metric for comparison. The dissociation scale of the ASDS was not included in the composite score as the IES-R does not include a parallel scale.

Acceptability
The process of conducting the intervention was viewed positively by the interventionists and supervisors who met weekly to review tapes of the sessions. Only minor changes in the treatment manual were made to increase clarity of steps in the protocol. Independent fidelity raters listened to tapes of sessions and reported that the therapists adhered to the manual 90% of the time and did so competently.

Data from the caregiver program evaluation form indicated that SCCIP-ND was viewed positively (e.g., that topics were important and helpful) and that the timing and format of the intervention was acceptable (Table II). For the item “The program helped us think differently about how cancer affects our family” there was more variability. Hand written comments on one of these questionnaires indicated that the participant felt that three sessions were not enough time for a family in distress to change. Other open-ended responses suggest the acceptability of SCCIP-ND and caregivers’ endorsement of the Multiple Family Video Discussion Group (MFVDG). Examples are “The video was an excellent resource. When you heard the feelings and emotions the families were expressing you definitely could relate (mother)”; “Not that we don’t discuss things, but with dealing with all the regular details of life, work and family and then the additional trips to the hospital etc., it was rare to have an hour in which we just would discuss feelings and relationships in regard to cancer and its treatment (father).”

Recruitment and Retention
Recruitment and retention of a representative sample is a common concern in intervention studies, particularly when the intervention involves accepting randomization to condition and commitment to research requirements.

<table>
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<th>Table II. Responses to program evaluation form</th>
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<tr>
<td><strong>Primary (N = 5)</strong></td>
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<tr>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td>The three-session format worked well.</td>
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<tr>
<td>The handouts and worksheets were easy to understand.</td>
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<tr>
<td>The timing of this program was appropriate.</td>
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<tr>
<td>We learned something new.</td>
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<td>The topics were important.</td>
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<td>The program was helpful to us.</td>
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<td>The program was interesting.</td>
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<tr>
<td>The program helped us think differently about how cancer affects our family.</td>
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<tr>
<td>The interventionist was tuned into our needs.</td>
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<tr>
<td>The program will help other newly diagnosed families.</td>
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<td>This program will help us to help our child.</td>
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Additionally, the SCCIP-ND protocol was intensive and involved two members of the child’s family. Data are presented pictorially in a flow diagram (Figure 1), following Consolidated Standards of Reporting Trials guidelines (www.consort-statement.org).

After identifying new patients of ages 0–17 years who were admitted to the Division of Oncology at CHOP from January 1 through June 30, 2003 (N = 88), forty-one families (46%) were determined to be ineligible for the following reasons: diagnosis (benign tumors, N = 17; cancer ruled out, N = 4; second malignancy, N = 1; second opinion, N = 1), type of treatment (resection or monitoring only, N = 8), patient transferred (N = 7), emancipated minor, (N = 1), and language (N = 2). Of the forty-seven eligible families, 28 (60%) declined participation. Reasons for refusal were – not interested (N = 9), unwilling to separate from the child (N = 5), overwhelmed (N = 12), or could not identify a second participant (N = 2). Our sample of 19 families represented a participation rate of 40%.

Disease and patient characteristics and family demographic variables indicate that the sample was representative of our larger patient population. There were no differences on these variables between the two arms of the study, documenting that the randomization process

![Figure 1. Surviving Cancer Competently Intervention Program—Newly Diagnosed (SCCIP-ND) Pilot Randomized Clinical Trial Flowchart.](https://academic.oup.com/jpepsy/article-abstract/30/8/644/1128529)
provided balanced groups. Two families in the treatment arm withdrew from the study. One family dropped out after T1 and before receiving a treatment session, indicating that they felt overwhelmed and expressing concern that they could not schedule sessions jointly. The primary caregiver in the other family withdrew from the study after Session 1 although the partner caregiver (grandmother) completed Session 2. The two families that withdrew were of ethnic minority backgrounds. There were no other observed differences in demographic or outcome variables between these families and others. One family completed Session 1 but not Session 2 or 3, due to a transition in the treatment team combined with scheduling difficulties. Given the intent-to-treat design, we collected T2 data and retained this family for analysis.

**Timeline**

Surviving Cancer Competently Intervention Program—Newly Diagnosed necessitates a brisk pace for intervention with families during a stressful period. To evaluate whether we could accomplish a three-session intervention within a month after diagnosis, we examined the length of time necessitated by discrete steps in the intervention procedure.

**Approaching families**

We were able to contact the majority of families within 24 hr of the meeting in which they were told their child had cancer.

**Length of time to obtain informed consent and complete Time 1**

Three families provided informed consent for the study within 24 hr of diagnosis. However, the process of consenting a family generally required two or three contacts. The median number of days from diagnosis to consent was 6 days, for both groups. With respect to the T1 assessment, the median for the treatment group was 0 days, indicating that it occurred immediately after consent for many families (the range was 0–10 days). For the comparison group, the median was 3.5 days, with a similar range (0–11 days).

**Spacing of three sessions and length of entire study**

The data indicate that Session 1 was generally held within a few weeks of T1 and that a comparable amount of time was necessary to complete Session 2. The length of time between Sessions 2 and 3 was substantially longer (Median = 25 days). Across all the data points, including the length of time from the end of Session 3 to T2 data collection, there was considerable variability and the time necessary to complete the protocol typically exceeded 30 days.

**Preliminary Outcomes**

**State Anxiety**

State-Trait Anxiety Inventory scores were elevated for primary \((M = 49.81, SD = 14.67)\) and partner caregivers at T1 \((M = 46.75, SD = 14.84)\) and were not significantly different between the SCCIP-ND and control groups. These scores were more than one standard deviation above STAI normative values \((M = 35.2, SD = 10.6)\), showing that the caregivers of these newly diagnosed patients were very anxious at T1.

Changes in mean scores between T1 and T2 by group showed a decrease in state anxiety for primary caregivers in the SCCIP-ND condition with scores at T2 within one standard deviation of the norm \((T1: M = 47.80, SD = 21.79; T2: M = 39.29, SD = 13.34)\) (Figure 2). Primary caregivers in the control condition showed no change in state anxiety across time \((T1: M = 51.22, SD = 15.28; T2: M = 51.50, SD = 14.32)\). For partner caregivers, state anxiety decreased between T1 and T2 for both arms, although the slope of decline was steeper for the SCCIP-ND group \((T1: M = 48.60, SD = 13.83; T2: M = 32.80, SD = 5.07)\) than the control group \((T1: M = 45.59, SD = 15.22; T2: M = 41.00, SD = 14.42)\).

![Figure 2. Changes in State Anxiety from Time 1 to Time 2.](https://academic.oup.com/jpepsy/article-abstract/30/8/644/1128529)
Parental Posttraumatic Stress Symptoms

Scores on our ASDS composite for primary (M = 34.81, SD = 9.68) and partner caregivers (M = 28.31, SD = 11.64) at T1 were consistent with data from a study of 274 parents of children in a pediatric intensive care unit (PICU) on the second day of their PICU admission (M = 34.40, SD = 12.47, Balluffi et al., 2004). IES-R data from this study suggests that PTSS levels at T2 for primary (M = 35.94, SD = 16.39) and partner caregivers (M = 28.61, SD = 22.80) are somewhat higher than the PICU sample at 4 months (median) after discharge (M = 28.57, SD = 24.91).

Transformations (z-scores) of the ASDS composite and the IES-R total score facilitated examination of the patterns of change in PTSS across time for the experimental and control groups (Figure 3). Both primary and partner caregivers in the SCCIP-ND arm showed declines in PTSS, whereas primary and partner caregivers in the control condition showed an increase in symptoms between T1 and T2.

Discussion

An evidence based family-oriented intervention to help caregivers and families during the early phases of their child's cancer treatment would represent a substantial advance in clinical care for children with cancer. The development of a brief-focused intervention that could contribute to the prevention and reduction of PTSS and anxiety for families is a broad goal of the present work.

In SCCIP-ND the researchers adapted our earlier intervention with survivors and their families, retained an integrated cognitive-behavioral and family therapy approach, and embarked on the ambitious goal of delivering the intervention to two caregivers per family shortly after diagnosis. In conducting this pilot study, our intent was to assess the overall apparent validity and acceptability of the intervention while also identifying issues related to the feasibility of conducting family interventions in pediatric oncology.

This pilot study suggests that SCCIP-ND has face validity and clinical relevance. This evaluation process is preliminary and awaits the results of a more rigorous evaluation in a larger RCT. However, as a second generation intervention from our laboratory, SCCIP-ND's apparent clinical usefulness builds on a treatment model used successfully with survivors of childhood cancer and their families (Kazak et al., 2004). The integration of a cognitive behavioral approach within a family therapy interpersonal context and focused on traumatic aspects of the cancer experience evolved from our earlier research and utilizes components of treatments with known effectiveness in other treatment contexts. Preliminary treatment fidelity data and program evaluation responses from participants yield further indications of the acceptability and clinical utility of SCCIP-ND.

The Multiple Family Video Discussion Group was an innovation introduced to provide a sense of normalization and connection with other families. The positive responses of caregivers regarding the video were encouraging. The video provides the opportunity to standardize the sessions in ways that in-person family discussion groups do not. That is, in the original SCCIP groups, there was variability across sessions in both content and process, whereas the video exposes all participants to the same material. Further developments using technology should be investigated as a means to enhance the delivery of family interventions without the complications of assembling groups of families.

Recruiting and retaining participants is critical for any research design intended to document evidence-based treatment. Our data on recruitment illustrated the many factors that affect attainment of a sample and argued for the wisdom of estimating sample size very conservatively. The participation rate for the study was 40%, which is below that expected for nonintervention research. Given few studies with which to compare this, the researchers think that this rate is not optimal but still acceptable. The major reasons for refusal (being overwhelmed, unwilling to separate from the child for the sessions) were understandable and provided information.
which can be used in subsequent intervention recruitment and design. Despite the recruitment challenges, the sample was representative of our broader patient demographics, including nine ethnic minority families. The families in the study were primarily two parent families and may represent a bias toward more highly educated and more affluent families. Examination of the participation of single parent families (e.g., their willingness and ability to identify an intervention partner) and families with fewer resources will be important in the subsequent larger trial of SCCIP-ND.

An important, and often overlooked step in intervention research is determination of whether dropouts are random. The loss of two families in the treatment group, both of whom were ethnic minority families, is of concern. Closer inspection indicated that these families were not of the same ethnicity, that they differed from one another in socioeconomic status and scores on the baseline measures, and that their reasons for leaving the study were not the same. Although difficult to interpret in this small sample, it will be important to continue to examine attrition closely in the future.

Across the phases of the study, variability in the timing of consent, baseline and follow-up data collection and the three sessions was striking. The data indicated that consent and baseline data collection can be completed within the first week or two of diagnosis. Examination of the flow of families through the study shows that more time elapsed between the later sessions than between the earlier steps. This is understandable in that families several weeks out from diagnosis are more often receiving most care as outpatients, with the child and family having returned to a routine with many competing appointments and demands. The need to coordinate the schedules of two caregivers also likely contributed to this pattern. The data highlight the importance of flexibility in scheduling, particularly when including multiple family members. The “cost” associated with flexibility is the increased variability in the timing of intervention delivery.

The data provide preliminary glimpses as to whether SCCIP-ND impacted caregivers’ state anxiety and PTSS. The pattern of changes seen in the families was consistent with expected outcomes. In this pilot investigation, primary caregivers in SCCIP-ND showed reductions in state anxiety from understandably very high levels at diagnosis to scores within normal limits two months after completion of SCCIP-ND, while those in the control arm did not show such reductions. There is comparable evidence for the reduction of PTSS in the SCCIP-ND arm relative to the control condition.

There are other potentially important outcomes which are being explored in the larger randomized clinical trial of SCCIP-ND currently underway. Although seemingly obvious that a family level measure would be optimal in a family intervention, our experience and knowledge of the literature supports the use of outcomes that are as specific as possible to the target of the intervention (Kazak, 2005). Unfortunately, family assessment measures are not necessarily specific to the goals of this intervention as they often assess more general dimensions of family functioning (e.g., communication styles, perceptions of closeness). In a brief intervention, it would be challenging to impact these outcomes along with the others. It is possible, however, that family constructs may also mediate or moderate other outcomes and should be explored further.

Another important outcome for all intervention research pertains to the potential benefit of psychological intervention on health care costs. In our current and subsequent studies, we measure the “cost” of psychological care in pediatrics by examining expenditures that are often overlooked (e.g., time spent by physicians and nurses addressing psychosocial concerns, team meetings for management of “difficult” families). It may be that effective psychological interventions at diagnosis could contribute to lower expenses and to an overall cost offset for the provision of psychosocial care. In another project we have identified a means by which psychosocial risk may be assessed at diagnosis (Kazak, Cant et al., 2003), with the longer-term goal of matching risk and intervention approach.

In summary, the issues addressed in this pilot study illustrate important processes in the development and delivery of family interventions to families of children newly diagnosed with cancer. Specific interventions, closely linked to empirical data regarding caregiver distress (in this case anxiety and PTSS) and provided at a key time in the course of cancer treatment (here proximal to the potentially traumatic events associated with childhood cancer) are promising for our ability to introduce more evidence-based intervention into pediatric psychology practice. This research is at an early stage of development. Nonetheless, documenting feasibility and identifying challenges in this work provides information that can be useful in the planning and implementation of broader innovative efforts to improve the well-being of children and families in pediatric healthcare.

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References


