Parents of children newly diagnosed with cancer experience depression and anxiety, especially in the first several months of treatment. Bright IDEAS, an 8 session problem-solving skills training (PSST) program has been used in studies with more than 900 mothers including more than 125 monolingual Spanish-speaking mothers. It has been shown to significantly decrease mothers' distress and to particularly benefit Latina immigrants. This past spring, the NCI/NIH designated Bright IDEAS as a Research-Tested Intervention Program and has included it in the National Registry of Evidence-based Programs and Practices. To date, Bright IDEAS has been available to mothers at only a few cancer centers with specially trained personnel. This proposal is designed to bring Bright IDEAS on-line to make it available to mothers *and fathers* 24/7 anywhere with Internet access. We will carefully analyze acceptability and use to gain insight into the most promising ways of disseminating interventions like Bright IDEAS using Internet and Internet II capabilities.

Research and experience document that caregivers of children with cancer encounter extraordinary stresses during the child's illness. These stresses are particularly severe during diagnosis and early therapy and can interfere significantly with a caregiver's ability to make reasoned and timely decisions on their child's behalf. With increasing survivor rates, it has become evident that decisions made in the early stages of cancer management can have profound long-term effects, adding to the distress caregivers feel trying to make the "right" decisions. Too help mothers of newly diagnosed children cope more effectively with these challenges, we conducted randomized controlled trials (R25CA65520, R01CA098954) to develop, field test, and evaluate the efficacy of the Bright IDEAS paradigm of problem-solving skills training (PSST), a cognitive-behavioral therapy shown to decrease anxiety and depression – two symptoms of post-traumatic stress commonly experienced among this group of mothers. Our findings clearly show that PSST significantly increases problem-solving skills (primary effect) and decreases negative affectivity (secondary effect) in mothers from a variety of racial, ethnic, and socioeconomic backgrounds. Particularly powerful and long-lasting effects were noted in Spanish-speaking mothers, an especially underserved population. In March 2010, the NCI designated Bright IDEAS as a Research-based Therapy/Intervention Program (RTIP) and entered it into the National Registry of Evidence-based Programs and Practices (NREPP). As an 8-session, in-person intervention, Bright IDEAS is labor intensive and, to date, has only been available at a few institutions with trained personnel. However, as a part of the RTIPs evaluation process, the Dissemination Capability of Bright IDEAS was rated 5/5. This proposal is designed to meet the challenge inherent in this perfect score. We will also immediately broaden the scope of users by including fathers as eligible participants in this study of a new delivery paradigm we believe they will find appealing. **Aim 1** is implementation of an engaging, easy-to-use on-line version of Bright IDEAS that would be available 24/7 to any person anywhere who has access to the Internet. **Aim 2** is the use of "*Diffusion of Innovations*" theory to craft a framework for disseminating not only Bright IDEAS but other similar interventions with the greatest effectiveness and efficiency. In past studies, we have shown that the human element (time and attention) inherent in in-person interventions is effective in bringing immediate relief of distress but not sufficient to maintain its benefits over time. In contrast, mothers receiving PSST increase their skills and continue to improve their sense of well-being 3 months after the intervention. What we have not investigated is whether a computer-based intervention is as effective as (not inferior to) an in-person intervention. The results will have significant implications for future dissemination strategies, especially the use of Internet II and other emerging technologies.

RESEARCH STRATEGY

(a) SIGNIFICANCE

Parental Adjustment to Childhood Cancer

Studies of social and emotional adjustment among parents of children, especially girls, with cancer suggest that some mothers and fathers are at risk for anxiety and depression.(1-4) Mothers, especially, are at increased risk for post-traumatic stress symptoms.(5;6) In fact, the incidence may be as high as 40%,(7) perhaps as a result of their concern for their child's life and their hypervigilence for signs of disease.(8;9) These findings are, however, not universal: early studies by Kupst et al. revealed no differences in psychologic functioning between parents of children with leukemia and control parents 1 year after diagnosis.(10;11) Similarly, Jurbergs et al(12) found no differences in posttraumatic stress in parents shortly after diagnosis, although symptoms did rise at relapse. Nevertheless, the overall literature supports the contention that mothers of children recently diagnosed with cancer are at increased risk for emotional distress.(13) Our group recently published findings in 212 mothers if children with newly diagnosed cancer who received no intervention within the first 9 months after their child's diagnosis. We found that, overall, mothers displayed mildly elevated negative affect and posttraumatic symptoms initially, with steady improvement evident 3 and 6 months after enrollment in the study. There were, however, three distinct trajectories of adjustment within the sample: high-declining negative affect/symptomatology, moderate-stable negative affect/symptomatology, and low-stable negative affectivity/symptomatology. These findings highlight considerable resilience among these mothers but also point to the need for intervention for those mothers at risk for on-going negative emotional responses.(4)

Relationship between Parental and Child Functioning

The emotional adjustment of children has been related to parental, especially maternal, reports of their own mental and physical health,(14;15) health beliefs,(16) coping strategies,(17) and perceptions of family and community social support.(18;19) It may be that increased social support, in particular, buffers parents from the adverse impact of stress. In turn, parents may buffer their children, protecting them from the deleterious effects of stressful experiences. In fact, family functioning and extrafamilial social support are significant predictors of adjustment in children with newly diagnosed cancer.(20-22) Similarly, in a report on maternal well-being and the functioning of siblings of pediatric cancer patients, Sahler and colleagues(23) found that, when healthy siblings were categorized according to their level of adaptation, lower levels of maternal well-being were correlated with less adequate adaptation among healthy siblings.

The Sahler et al study of siblings of children with cancer,(23) found that mothers of poorly adjusted siblings coped by accessing more resources than did mothers of well-adjusted siblings. Interestingly, however, mothers' level of satisfaction with their resources was remarkably low. Whether their dissatisfaction was due to accessing the wrong resources, to their inability to articulate their needs clearly enough to obtain appropriate help, or to their inability to effectively apply whatever advice was offered is unknown. However, these findings led us to hypothesize that a systematic method for teaching mothers of children with cancer how to identify and solve problems would reduce their stress levels and increase their levels of self-satisfaction and well-being.(24)

Special Issues of Spanish-Speaking Hispanic Mothers as an Example of an Underserved Minority

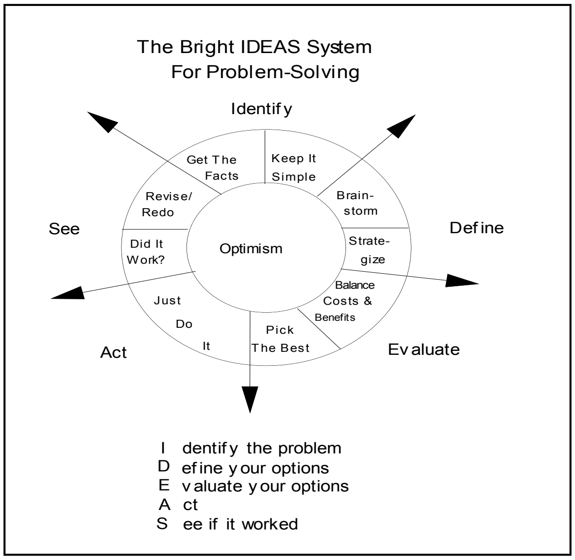
At two of our sites (Childrens Hospital Los Angeles, UT/MD Anderson Cancer Center), the percentages of Hispanic families seeking pediatric oncology care currently averages ≥60%. Spanish-speaking mothers are at increased risk for traumatic stress reactions associated with their child's illness.(25;26) Immigrant mothers with limited English fluency have difficulty communicating and understanding complex medical systems, and are more likely to experience their child's situation as severe and life-threatening.(25;27-30) Even without an ill child, the difficult and often dangerous process of immigration and acculturation means the loss of supportive familial, social, and cultural relationships, higher levels of poverty, interrupted maternal education, and increased emotional demands and distress.(31-33) These life experiences can exacerbate the perceived stress of a child's illness.(25;26;34) In the first study of traumatic stress symptoms in monolingual Spanish-speaking mothers of pediatric cancer patients using standardized assessment instruments, Hart & Katz, et al.(26) found 35% of mothers reported moderate to high levels of distress, a rate similar to that of primarily Caucasian English-speaking mothers.(7) However, Spanish-speaking mothers experienced higher levels of severe avoidance symptoms, and they tended to perceive lower quality of life in their ill children. A recent qualitative analysis of the coping methods of Latina vs. European American demonstrated the expected differences in coping styles based on culture that might not be appreciated by majority providers.(35) Lastly, maternal education has been found to be significantly inversely associated with traumatic stress symptoms(36) and higher education has been found to be associated with better problem-solving skills. Recently immigrated Spanish-speaking mothers typically have less formal education.

(b) INNOVATION

Bright IDEAS Paradigm of Problem-Solving Therapy

Problem-solving therapy (PST) is a 5-step cognitive-behavioral therapy by which individuals learn to use problem-solving skills to cope effectively with stress and emotional distress,(37;38) depression, anxiety, and adaptation to chronic health(39) as well as life-threatening conditions.(40) First conceptualized by D'Zurilla and Goldfried,(41) the treatment has been applied widely by Nezu, Nezu, and D'Zurilla to many life situations.(42)

In contrast to problem-solving therapy, problem-solving *skills training* (PSST) is a term we have chosen to use when applying the PST approach to individuals who, as a group, are distressed but do not manifest psychopathology or clinical levels of emotional distress such as severe depression or a diagnosed anxiety disorder. In this context, PSST has been successfully used with newly diagnosed pediatric cancer patients as part of a social skills intervention for school reintegration,(43) adult cancer patients to enhance overall mood, and caregivers of adult patients with cancer(44) and other chronic health conditions(45) suggesting that PSST has potentially very wide applicability.



In the early 1990s we developed a PSST intervention for mothers of newly diagnosed childhood cancer patients. It consisted of 8 1-hour individual sessions conducted according to a detailed protocol. PSST was offered as a generic coping skill applicable to a range of problem-based and emotion-based stressful situations commonly encountered during early treatment of childhood cancer. The specific problems discussed during the intervention were identified by the individual mother as especially relevant to her and her family. The intervention was presented by a master's level mental health professional or a doctoral candidate in psychology.

To make the overall philosophy and steps of the PSST program more easily understood and remembered, the acronym **"Bright IDEAS"** and the logo of a lighted bulb were developed. The bulb signifies the sense of **optimism** (positive orientation) about solving problems that is essential for successful implementation. The letters **I** (**I**dentify the problem), **D** (**D**etermine the options), **E** (**E**valuate options and choose the best), **A** (**A**ct), and **S** (**S**ee if it worked) signify the five essential steps of problem-solving as articulated by D'Zurilla and Nezu and reinterpreted by us.(24) Instructional materials include a treatment manual, summary brochure, problem-solving worksheets, and trigger cartoons. The mother receives a verbal overview of the intervention, a parents' manual, and an 8-page pocket-sized Bright IDEAS pamphlet that summarizes the steps of problem-solving with examples. Each week, participants are given a "homework" assignment to identify and solve a problem of immediate interest to them. Their effort is reviewed at the following session.

The conceptual model below has provided the general framework for all our studies, which now have assessed the benefits of PSST in >900 mothers of newly diagnosed childhood cancer patients.

Based on the critique we received when we were designated one of the RTIPs that would be entered into the NREPP, it was clear that our intervention is highly valued and is seen as readily disseminable. **Thus, our proposal is designed to implement Bright IDEAS in a delivery vehicle that lends itself to 24/7 access by parents anywhere in the world linked to the Internet. Given the wide appeal of the approach to many populations experiencing depression or anxiety, we believe that electronic availability will permit many individuals to profit from our work. Because the study design includes careful, extensive debriefing of a subset of participants that, by design, includes an over representation of Spanish-speaking Latino parents, we will extend and improve our accessibility not only to the general public but also to this minority population as a *prototype* for dissemination among other immigrant groups. Lastly, this is the perfect opportunity to assess the impact of reducing the human element from an intervention that has**

been designed, implemented, and evaluated as an in-person treatment. As noted below, PSST has a therapeutic effect that exceeds the time and attention associated with delivery. WE WILL NOW ASSESS IF THE CONVERSE IS TRUE. That is, our findings will have major implications for how therapies are moved from in-person to the Internet including social networking to answer: Is the inherent social support of PSST, derived from working with an interventionist face-to-face, essential for effectiveness?

(c) APPROACH

Previous Studies

The collaborative investigative network that has developed and assessed PSST in childhood cancer has been in place since 1988. The current group is an outgrowth of the Sibling Adaptation to Childhood Cancer Collaborative Study funded by the WT Grant Foundation (1988-1993). We have conducted three randomized, controlled multi-site studies of PSST: (1) a one-on-one PSST pilot study with 92 mothers of children recently diagnosed with any form of cancer/brain tumor (conducted in English in the US and in English and Hebrew in Israel); (2) a multi-arm English-language, Spanish-language, and computer-assisted PSST study with 430 participants (Phase II) from the same subject population; and (3) a multi-arm English-language, Spanish-language, and personal digital assistant-assisted PSST study with 402 participants.

Our findings have shown consistent improvements in problem-solving skills that have partially mediated significant reductions in negative affectivity (depression, anxiety). Our most recent finding, which was just presented in May 2010 at the Pediatric Academic Societies Annual Meeting, demonstrated that, when compared to an active time-and-attention control ("reflective listening"), PSST mothers had better PSST skills but were otherwise indistinguishable in negative affectivity from control mothers immediately after the intervention (i.e., both groups showed improvements). HOWEVER, when assessed 3 months later, the mothers in the control group were beginning to plateau in negative affectivity whereas PSST mothers were continuing to show even greater improvements resulting in significant between-group differences.. We have adopted the anonymous saying: "Give a man a fish and feed him for a day; teach a man to fish and feed him for a lifetime" to explain these results. That is, the skills taught mothers in the early post-diagnosis phase of their child's illness are really generic skills that can be applied not only in subsequent cancer-related situations but also, in fact, to any life stress.

Recent Selected Productivity <u>2005-Present</u>

Problem-Solving Skills Training (PSST) Publications/Presentations by Consortium Members

Over the past 5 years, we have reported our findings in multiple journal articles and at numerous professional meetings as peer-reviewed or invited presentations. The research consortium has published 6 major peer-reviewed journal articles (1 in the *Journal of Consulting and Clinical Psychology,* 4 in the *Journal of Pediatric Psychology,* and 1 in the *Journal of Pediatric Oncology Nursing)*, made 25 peer-reviewed presentations before national/international organizations, and written 2 book chapters. In addition, members of the research consortium have given more than 15 invited presentations to regional and national groups about the Bright IDEAS paradigm.

Importance of Our Past Findings

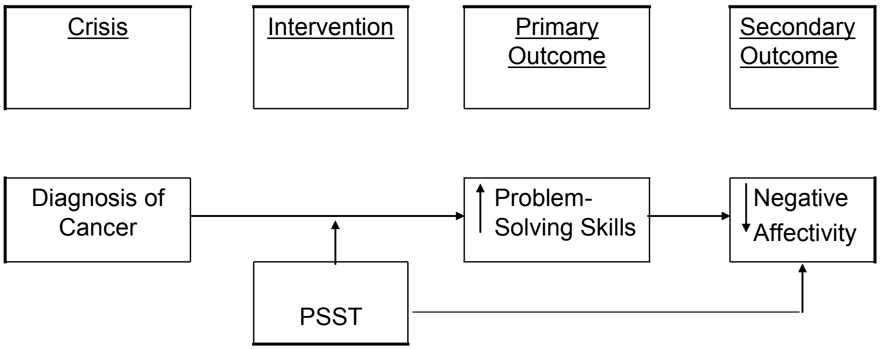
During the early months after diagnosis, parents are faced with many critical decisions regarding a multitude of treatment options for their child who has a life-threatening disease. It is well accepted that emotional distress can interfere with sound and rational cognitive processing under the best of circumstances, let alone in the context of complex information overload. In addition to understanding the consequences of decisions about treatment options, mothers are also confronted with deciding how to handle the logistics of caring for their child during induction and consolidation treatment (e.g., to work outside the home or not; insurance coverage; out-of-pocket expenses staying at the hospital; running the household), decisions about how to handle other children in the family (e.g., providing information and reassurance; juggling time and attention which children equate with love and caring), and coping with the stress and uncertainty of family and friends as well their own. Thus, helping them to feel more confident about their decision making in any of these realms helps reduce tension and anxiety. We have termed this significant benefit of PSST **"avoided distress."** We contend that helping to reduce distress during this critical, early stage of their child's illness and treatment makes mothers more available to successfully manage the complex tasks they face of managing their ill child, their family and their own personal responsibilities.

Limitations and Challenges of Our Current Intervention
Two major challenges still face us: (1) decreasing the labor intensiveness of the intervention; and (2) increasing ease of use and accessibility for all parents of a child with cancer beyond having specially trained professionals at designated institutions.

Potential Solution
Developing a web-based PSST intervention appears to us to be the most logical next step in enhancing Bright IDEAS. It is essential to note that we partnered with the Information Systems Institute of the Department of Engineering at USC to develop an "Intelligent Agent" (aka Carmen) approach to capturing and sustaining mothers' attention using animated characters in the early 2000's.(46) The delivery vehicle was a program that was loaded into a PC. In 2005, we developed a PDA-based version of Carmen in a program entitled DESIA. Both of these applications suffered from the limitations of then-current technology, in particular, marginal ability to update and repair the intervention because of its static programming features. We see a Web-based approach as an excellent solution to the need to provide ongoing logistical support, intervention updates, and repairs. We envision the utilization of various Web 2.0 features as a means of offering social network support, thus addressing the potential social support disparities between a computer-based system and an in-person intervention. That is (as noted above), we have shown that the easing of distress from in-person PSST is the same as that garnered from an active time-and-attention control immediately after the intervention; but PSST is far superior over time because of learned skills**. What we do not know is whether on-line PSST WITHOUT person-to-person contact will be as effective or, at least, not inferior to in-person PSST.**

The current proposal provides us with a unique opportunity to study the human element of in-person interventions by using the principles grounded in participatory processes(47;48) and diffusion of innovations theory.(49;50) This exciting element of our move to the Web will provide insight into how parents of newly diagnosed patients gather information and support from their environment. This application could serve as a *prototype* for investigating information gathering and dissemination within a broad segment of the US population.

Conceptual Model



METHODS
The primary aim of this 2-arm RCT is to develop, implement, and evaluate the comparative effectiveness of two active interventions: face-to-face PSST (standard PSST) and on-line PSST (e-PSST). Participants will be a parent of a newly diagnosed child. The primary aim of the intervention will be to increase problem-solving skills and decrease negative affectivity (e.g., depression, anxiety). (See conceptual model). The secondary aim will be to study the dissemination of PSST using online strategies. To make this transition as universally appealing as possible, we will include fathers as participants and we have two consultants working with us (A. Singhal and L. Dura) who have extensive experience working in the dissemination of health education in Africa, South Asia, India, and South America. Although it is impossible to engage all of these cultural/ethnic population groups in a study based in the US, we will apply their expertise gained in other countries to the development of prototypes for use with minority immigrants who have a child with cancer.

To test intervention effects on outcome measures, subjects will be assessed on standardized measures at Time 1 (T1, pre-intervention), Time 2, (T2, immediately post-intervention), and Time 3, (T3, 3-months post). A subset of English- and Spanish-speaking parents will participate in in-depth interviews to discover emergent possibilities and vehicles for dissemination. (See Methods for Aim 2 below)

Four institutions in our collaborative research consortium (UT/MD Anderson Cancer Center, Children's Hospital of Pittsburgh, Childrens Hospital Los Angeles, and St. Jude Children's Hospital) have agreed to serve as data collection sites, and Diane Fairclough, DrPH, has agreed to again serve as the Co-Investigator for biostatistics and data management. Two investigators with much experience delivering and studying PSST (Drs. Dolgin and Sherman) will serve as consultants to provide Treatment Integrity monitoring. Joint training sessions for PIs and RAs, consistently held meetings in-person and by conference call, and joint responsibility for data collection and statistical analysis will ensure ongoing cooperation and collaboration.

Project Timetable

See Overall Project Timetable to the right.

Overall Project Timetable

Month	Tasks
1	Senior Investigator/consultant meeting to begin project tasks
13	Complete development and field testing of e-PSST (in English and Spanish)
14	Senior investigator meeting and research assistant training Begin randomized trial: Standard PSST vs. e-PSST
49	Complete subject recruitment
55	Complete data collection
56	End-of-project senior investigator meeting to review data analyses
60	Complete project, report results, close out

Subjects

Eligibility Criteria

Subjects will be drawn from the pool of all parents who are primary caregivers of children diagnosed with any form of cancer 4-16 weeks prior to contact about the PSST intervention and cared for at one of the 4 data collection sites (dense sampling). No attempt will be made to stratify the sample by any particular demographic variables (e.g., age, ethnic background, or type of cancer diagnosed in their child), except that monolingual Spanish-speaking parents will be specifically recruited to provide adequate representation for statistical analysis at Childrens Hospital Los Angeles and UT/MD Anderson Cancer Center. Goal: 20% total enrollment.

Diagnosis Restriction

None. Accepting parents of children with any form of cancer increases generalizability.

Exclusionary Criteria

Parents of children with cancer will be excluded if (1) they do not read or speak English or Spanish; (2) their child is in severe a medical crisis, as determined by the oncologist, or (3) they live a prohibitive distance to complete the intervention (typically, >50 miles from the Center) and do not have access to a telephone for phone intervention sessions. Internet access will be facilitated as part of the e-PSST intervention arm. These exclusionary criteria are identical to our previous work; <10% of eligible mothers have been excluded.

Non-Participants

A list of possible participants with reasons why they did not participate (e.g., scheduling problems) will be maintained and submitted to the data management center each month. A contact form with minimal demographic information and reasons for non-participation will be submitted for each parent approached to allow us to calculate refusal rates and describe the population of non-participants.

Terms of Participation and Incentives

Each potential participant will receive a written description of the study, its goals, and the randomization procedure. Those who agree to participate will sign an informed consent document outlining the nature and duration of participation as approved by the Institutional Review Board of the Center where his/her child receives care. Each individual who agrees to participate will complete a 1-hour baseline assessment prior to randomization. Specific learning objectives and outcome measures for each session are included in the PSST Parent Handbook (see below and Appendix A). The immediate post (T2 10-12 weeks) and 3-month post (T3 weeks 17-23) evaluations will be conducted as additional sessions. Subjects will receive a stipend of $25 when each of the T1 and T2 assessments are completed and $50 when the T3 assessment is completed.

Potential Subject Pools and Recruitment Expectations by Site

SITE	New Dx/yr (# Spanish)*	Target Recruitment/3 years		
		English	Spanish	Total
Children's Pittsburgh	120 (N/A)	155	--	155
Childrens LA	325 (200)	80	75	155
St. Jude	225 (NA)	155	--	155
UT/Anderson	325 (65)	105	50	155
TOTALS	**995 (265)**	**495**	**125**	**620**

*New diagnoses **PER YEAR**. Target numbers given for each language group represent **3** years of recruitment producing a total pool of ~3000 mothers. Past recruitment rates have ranged from 55%-90%. Each center has agreed to recruit the same number of subjects despite differing numbers of new diagnoses/year. Individual commitments take into account likely competing protocols, prior commitments still in effect when the study begins, and past experience.

Recruitment

Recruitment will occur between 4 and 16 weeks, typically during induction or early outpatient treatment visits. Recruitment routines vary by institution, but are systematic (e.g., not identifying potential candidates based on evidence of or lack of problems) and will be approved by each individual Institutional Review Board. English-speaking parents are more likely to agree immediately, whereas, in our experience, Spanish-speaking parents have required greater outreach and more explanation to other family members. Every effort will be made to assure complete participation (follow-up calls, flexible scheduling, home visits).

Randomization and Data Collection Procedures (See statistical considerations below)

Methods Aim 1 (Development and Implementation of Two Forms of Bright IDEAS Paradigm of PSST)

Website Development

The first 13 months of the project will be dedicated to development of a web-based version of Bright IDEAS. The site will be constructed by Radiant Creative Group, a private firm with significant web development experience and notable expertise in the implementation of online behavioral intervention programs. Site development will occur at UT/MDACC under the immediate supervision of Dr. Martha Askins. The Radiant and UT/MDACC teams will collaborate to develop, document and implement all site features, interactive activities, and supporting media components. During site development, Radiant will employ an iterative and evolutionary systems development process based on agile software development methodology, a conceptual framework that promotes the development of releasable units of software in rapid, iterative fashion. This approach emphasizes the quick delivery of multiple prototypes and incorporation of user input/feedback into each product release. The goal of an agile process is to better manage risk and create a more effective, user-focused product. The overall process and project performance will be continually monitored to ensure that risks are predictable and can be managed effectively.

e-PSST Development: Tasks and Milestones

Task	Months	Primary Responsibility	Milestone
Project Planning Application Requirements	1-2	Radiant	Requirement set, content inventory, message matrix
System Design	3	Radiant	UI design treatment Application design, test plan
Construction	4-11	Radiant	Completed website
Integration and Testing	11-13	Radiant	Validation of all site features to test plan
Deployment	14	Radiant	Released website
Application Support	14-60	Radiant	As needed
Infrastructure Support	14-60	MDACC	As needed

The development process will be conducted in several phases - *Planning and Requirements Analysis, Design, Construction, Integration and Testing, and Deployment*. The product will undergo multiple rounds of plan-based testing, including automated tests, validation, verification, and informal usability testing. The website will incorporate features for interactive intervention delivery, data collection, usage monitoring, issue tracking, and ongoing technical support. It will have the following characteristics:

- As the study will be site-based, the web-based system will support a hierarchy of roles, and will incorporate controls for site-based information privacy.
- The web-based intervention will consist of 8 lessons*
- Each lesson will incorporate 1 to 3 streaming videos, including an introductory video delivered by a counselor to provide lesson orientation
- Video modeling will be used throughout the intervention when appropriate. We anticipate that a total of 24 modeling videos will be produced
- Five interactive activities (one activity per process step) will be developed in order to enable users to practice and master each step in the IDEAS model
- The previously developed PDA application (DESIA) will inform development of a core "homework tool"
    - Site developers will re-use the existing message library
    - Site developers will implement application logic according to the original PDA application design documents
- To ensure compliance with HIPAA and state-level information privacy rules, Psychosocial Measures will not be collected online.

*(Although only 6 “lessons” will used for this current project (session 1 will be in person to fully explain the research project and session 8 will be in person to reinforce completion of T2 and T3 assessments), economy of scale dictates that all 8 sessions eventually required should be developed at this time.)

Following the website launch, application support will be provided by Radiant on an as-needed basis for the duration of the project including any redesign indicated by the interim analysis (see statistical analysis section). The website will be hosted by UT/MDACC’s Internet Services Group. UT/MDACC has a firewall-protected, HIPAA compliant institutional Web server infrastructure, and provides support services.

User-focused intervention design

Throughout web site development, the Radiant/MDACC team will employ a user-driven, patient-informed approach to ensure the online intervention is relevant, appealing, and highly usable. User feedback will be collected at regular intervals, and we will use structured qualitative focus groups and informal usability testing.

We will conduct two cycles of focus groups; participants will be recruited from the primary MDACC site pool. The first focus group will be completed during early system ideation, and will examine topics related to participant needs and potential barriers and incentives to using the web-based intervention. During this session, participants will review prototype design documents, sketches, and mock-ups, and the project team will gather feedback related to web program concepts, features, and style. The development team will utilize critical feedback or ideas uncovered during this session to guide preparation of the first application prototype. A second focus group cycle will be conducted following the “alpha” system release to gather additional information about participant’s experience in using the prototype. Discussion topics during this session include: impressions of the overall program, and the basis for those impressions; perceptions about how the program appeals to participants; relevance of program elements to their personal experience; appropriateness of messages and media (e.g., graphical and textual components, video); and desire for additional information and/or improvements to the program. Again, feedback will guide revision. Each session will involve a group of 8-10 participants with modest compensation for participation in these events. Broadly accepted methods of conducting qualitative studies described by Krueger and Casey(51) will be employed. Ethnographic software will be used in data interpretation, systematization, and presentation.

In addition to focus group evaluation, we will conduct a minimum of two cycles of usability analysis during the web intervention development cycle to ensure that participants are able to effectively understand and use the website interface. During these testing cycles, we will recruit 5-7 participants, and will implement an informal usability testing protocol involving the completion of a series of navigational tasks. An observer will record user behavior in order to identify any interface-related roadblocks or challenges. Suggested modifications will follow.

All evaluations will be conducted in the Behavioral Research and Treatment Center at MDACC. During both focus group and usability testing, we will attempt to recruit participants who represent all ages in our target range, and we will attempt to effectively balance our sample in terms of gender and ethnicity

Website Platform Considerations

Broad technology trends indicate that Internet usage (cell phones, tablets, other wireless devices) will eclipse desktop Internet access by 2015.(52) Additionally, mobile Internet access tends to invert certain socio-conomic Internet technology adoption trends. Data from the Pew American Life project indicates that mobile use among African Americans and Hispanics outpaces that of white, non-Hispanics, and this is particularly true for mobile data access. For instance, 87% of Hispanics own a mobile phone vs. 80% of whites; 51% of Hispanics who own a phone use it to access the Internet vs. 33% of whites.(53) Internet access trends related to household income levels have also been observed: 40% of households with income levels <$30,000 per year have Internet access at home vs. 75% of those same households own mobile phones.(54) Therefore, a priority of our website intervention development project will be to produce a system that is deliverable across a broad range of internet-connected desktop *and* mobile devices, thereby increasing opportunities for electronic dissemination and better serving the needs of our diverse target population. We will accomplish this via the following technical strategy: 1) implementation of an intentionally simple user interface in order to accommodate devices with limited screen real estate and control interfaces; 2) utilization of programming practices that accommodate graceful degradation of the presentation layer on less-capable devices; 3) adherence to widely accepted standards-based development practices (e.g., W3C validated presentation layer code); and 4) implementation of static testing across a variety of mobile and tablet devices.

PSST Interventions

After completing the T1 (baseline) assessment, parents will be randomized to either the standard PSST arm or the e-PSST arm.

Standard PSST consists of 8 1-hour face-to-face sessions held at the hospital/clinic, at the parent's home or other convenient location, or by telephone. Each encounter will be audiotaped and then uploaded to a secure site for storage and random Treatment Integrity testing. After session 8, the participant will complete the T2 assessment; three months later, he/she will complete the T3 assessment, which will include a brief questionnaire about the usefulness of the intervention. Following the T3 assessment, 5 participants at each of the four data collection sites will be selected to participate in the diffusion of innovations (Aim 2) process.

Online or e-PSST consists of an initial face-to-face meeting between the parent and the research assistant (RA) for an in-depth explanation of Bright IDEAS, and an explanation of the application that will be available on the Internet through the parent's own lap/desktop or mobile device. If a parent does not have reasonably convenient Internet access, an inexpensive Internet communication unit will be loaned to the parent for the duration of his/her participation in the project. The second through seventh weekly sessions will be held on-line. Prompt .logistical support will be available throughout the week from the developer. Content or intervention questions will be emailed to the site RA for a response no later than the next business day. The eighth session will be face-to-face to reinforce principles learned (relapse prevention) and emphasize PSST as a generic skill that can be used in virtually any logistical or emotion-focused problematic situation. After session 8, the participant will complete the T2 assessment; three months later, he/she will complete the T3 assessment, which will include a brief questionnaire about the usefulness of the intervention. Following the T3 assessment, 5 participants at each of the four data collection sites will be selected to participate in the diffusion of innovations (Aim 2) process.

Comparative Assessment of PSST Effectiveness

Measures (see Appendix B for measures) Except for minor changes to our demographic form, measures are identical to those in previous studies to continue to accumulate replication data. All measures except for Demographic Information will be administered at T1, T2, and T3.

Demographic Information

Includes information about the child with cancer (age, diagnosis, date of diagnosis), parental age, marital status, educational level, occupational prestige of the family, and previous experience with the Internet.

Social Problem-Solving Inventory-Revised (SPSI-R)(39;55;56) is a 52-item self-report measure derived from a factor analytic study of the 70-item original. The SPSI-R measures two dimensions of problem orientation (Positive/Negative) and three dimensions of problem-solving (Rational/Impulsivity-Carelessness/Avoidance. The SPSI-R is characterized by strong reliability and validity estimates.

Negative Affectivity/Mood State

The Beck Depression Inventory-II (BDI-II)(57) is a 21-item self-report assessing the cognitive, affective, and behavioral components of depressive symptoms. It is widely used for clinical and research purposes. Internal consistency ranges from .73 to .92, with good test-retest reliabilities cited in the manual. The BDI-II has been used to assess the relationship between problem-solving ability and depression and is included, in addition to the Profile of Mood States Scale and Impact of Event Scale (below), to investigate replicability of past findings.

The Profile of Mood States (POMS) Scale(58) is a 65-item self-report about feelings over the previous week It measures six moods or affective states (tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment). Internal consistency, test-retest reliability, and validity are acceptable. It is completed in 5 minutes, requires 7th grade reading ability, and is sensitive to change.

The Impact of Event Scale-Revised (IES-R)(59) a 22-item self-report measuring perceived post-traumatic stress, includes three subscales (intrusion, avoidance, and hyperarousal) that assess PTS symptoms (PTSSx) during the past week experienced in response to a specific event. Widely used to measure PTSSx associated with events such as diagnosis with cancer. Internal consistency reliabilities of the intrusion, avoidance, and hyperarousal subscales are .91, .84, and .90, respectively.

Acculturation

Hispanic Stress Inventory (HSI)(60)-(61) (Spanish- and English-speaking Latino/a subjects only) The 18-item Immigrant Stress subscale of the HSI has acceptable reliability and validity within the Hispanic population. It assesses culturally specific stressful life conditions among adult immigrants. Alpha coefficient is .85; test-retest coefficient is .80.

The Bidimensional Acculturation Scale for Hispanics (BAS)(62) (Spanish- and English-speaking Latino/a subjects only) provides an acculturation score for 2 major cultural dimensions (Hispanic and non-Hispanic domains) by including 12 items (per cultural domain) that measure 3 language-related areas. The Short Acculturation Scale for Hispanics was used to establish concurrent validity. Internal consistency and validity coefficients are high. The scale can be used with Mexican Americans and Central Americans.

Qualifications and Training of Research Assistants (RAs)

Qualifications

The RAs trained to deliver PSST will be master's level mental health professionals or doctoral candidates in psychology who have completed >2 years of study in a counseling-related field (e.g. clinical psychology) or have equivalent experience. Their careful attention to detail and ability to constructively critique issues related to implementation of both forms of PSST will provide useful information about how PSST can eventually be delivered in real-life situations at centers with modest psychological resources. Please see Diffusion of Innovations section below (Aim 2).

RA training occurs at a 2½ day workshop during month 13. We have conducted 4 similar workshops in support of previous PSST projects, resulting in standardized training, enhanced RA understanding of and commitment to the project, and greater collegiality. We will also include the RAs in quarterly all-investigator conference calls to share recruitment strategies and identify logistical concerns. The workshop agenda provides a template for training replacement RAs.

Treatment Integrity (TI)

We believe integrity of treatment implementation (i.e., assurance that interventions are conducted as intended and by a competent therapist) is a critical feature of well-controlled outcome research.(63) Although the use of manuals and cohort training of RAs, which this proposal provides for, do much to address this issue, systematic assessment of integrity must be conducted to draw firm conclusions about differential treatment effects, if any.(64) Tests of TI are also important when interventions are conducted at multiple sites by different providers to identify any confounding site effects. To assure TI, all trained RAs will be supervised by their site PI at a rate of 1 hour/4 hours of subject contact except for the initial three sessions conducted by an RA, all of which will be reviewed in depth by the site PI. Also, every session will be audiotaped, identified only by subject code, and uploaded to a secure site maintained by the data management center. 10% of the standard PSST tapes will be chosen at random by the center for review by either the English-language or Spanish-language reviewer according to a checklist of content items and personal responses that we have used for prior projects; 20% of the first and last session tapes with parents in the e-PSST group will also be chosen for review. Feedback about any TI concerns will be delivered through the center to the respective RA and Site PI. Interrater reliability will be checked at least every two months. The TI group will also review usage data from the on-line sessions monthly to determine if parents are accessing the website consistently across sites.

Site Audits

Each data collection site will be audited in-person twice during the recruitment/data collection phase of the study to assure that all IRB and study data collection and storage requirements are being met. These audits will be in addition to any institutional audits.

Methods Aim 2 (Exploration of Strategic Dissemination of Bright IDEAS Paradigm of PSST and Other Similar Interventions)

The focus of Aim 1 of the current randomized, controlled trial of Bright IDEAS PSST is to determine the relative effectiveness of the primary delivery medium, i.e., face-to-face vs. online. As a *complement* to Aim 1, the focus of Aim 2 is to conduct qualitative usability research with a subset of both face-to-face and on-line users.

Results will be used to develop a strategic dissemination plan that will maximize the likelihood that research findings and best practices generated from the Bright IDEAS program are appropriately documented, shared, and utilized beyond the scope of this single intervention.

Data for Aim 2 will be gathered through in-depth, semi-structured interviews to map the users' (mothers and fathers) interactional world, and will be analyzed using the constant comparison method.(65-70) so that emergent, usable possibilities and interfaces(47;48) for dissemination of Bright IDEAS can be strategically identified. In using the constant comparative method, respondent groups are chosen for theoretical rather than statistical reasons.(66;69;70) Samples are not chosen randomly; rather respondents are selected strategically. In this case, we will aim to include 20% Latino/a participants and at least one father in each group of 5 (see below).

The design for Aim 2 comprises in-depth interviews with 5 face-to-face users and 5 online users of Bright IDEAS at each of the 4 sites, for a total sample population of 40 mothers and fathers. Spanish speakers will be included in this sample at two sites: UT/MD Anderson Cancer Center and Childrens Hospital Los Angeles. They will be recruited to comprise a goal of 20% of the sample. Data gathering will be by both individual interviews and focus groups. Given our goal of 20% Latino/a representation, we will aim for two Spanish-speaking participants in each of the groups at MD Anderson and CHLA since none are anticipated at Pittsburgh or St. Jude. We will also aim for one father in each of the 5-member groups (8 fathers of the total 40 participants in Aim 2). A "friendship model" of interviewing will be employed - one that conceives of trust as being developed through research, encourages the researcher to be responsive to the respondents, and creates a space for respondents to not just answer but also ask questions.(65;71-73) This allows for the emergence of spontaneous, unanticipated, but germane, issues to arise. Data collection for Aim 2 will not begin until all data for Aim 1 for a given interviewee has been collected to avoid "over thinking" responses to the standard measures. More information on guiding research questions, an example of a possible interview structure, and a detailed account of the steps involved in constant comparison analysis are in Appendix A.

Statistical Considerations

Randomization

Randomization assignments will be balanced within site and language using an undisclosed block size. We anticipate enrolling few fathers and so will not randomize by gender. Randomization will occur centrally upon receipt of eligibility data from a participating institution. After ascertaining eligibility and obtaining consent, pertinent registration information will be entered through an Internet site at the Data Management Center (DMC). To insure confidentiality, a log-in ID and password will be required. Registration information will not include protected health information, the participant's name or any contact information. A back-up procedure will be in place in the rare event that Internet communications fail for a 24-hour period. We have successfully used this system for 4 prior projects. NOTE: A separate drawing of 5 names each (drawn at least until one father is included) from the standard PSST and e-PSST groups at each site will be used to identify participants to be recruited for Aim 2 from among all participants who completed the intervention. Assessment data from these participants will be identified only by subject number. All data will be aggregated and reported only by study arm.

Aim 1: Quantitative Data Management

Data Collection Procedures

All data forms will be checked immediately at the collection sites to insure completeness. The RAs will ensure no question was skipped unintentionally and will encourage a response. If an entire assessment or any component (scale) was not completed, the reason will be documented on the "Assessment Summary Form."

A readable copy of the forms will be forwarded (within 1 week) to the DMC, with originals retained for local documentation. Once the information is received by the DMC, centralized data editing will be conducted to ensure completeness and readability. Questions/corrections will be addressed to the site for resolution. The data will then be entered into the relational database for tracking through the project. All forms will be double entered. To facilitate T2 and T3 follow-up, the DMC will notify sites of upcoming assessments monthly. *We will ask all participants to complete all follow-up assessments regardless of whether they have completed PSST.*

Data Analysis

Although the proposed trial will provide a wealth of data for analysis, to guide future therapy more effectively it is important to identify a primary analysis *a priori*. We propose a Non-Inferiority test of the online vs. standard PSST. The null hypothesis is that the difference (online-standard) in the effects of the two interventions (D) is less than the magnitude of the margin of equivalence (E). E is the largest difference that is not of practical significance (H0: $D <= -|E|$). The alternative hypothesis is that the difference is greater than E

(H1: D> -|E|). Basically, non-inferiority is demonstrated if the confidence interval on D excludes values <|E|. The primary analysis will be performed on an "intent-to-treat" basis; i.e., once a subject is randomized, data on that subject will be analyzed according to their assignment, regardless of whether or not the subject actually completes the intervention. Every effort will be made to reduce attrition and to obtain follow-up data. Steps will be taken to avoid missing data, including careful instructions, offering assistance, and making follow-up calls. If necessary, strategies for handling missing data will be chosen based on the type, nature, and extent of the problem, and could range from replacing a single item on a scale with the mean of the subscale, dropping a subscale or measure, or multiple imputation for the primary endpoints.(74)

General Considerations

Analyses will be performed using maximum likelihood estimation (MLE) for incomplete repeated measures (SAS Proc Mixed).(75;76) Thus: (1) All available data can be included in analyses even when there is missing data at follow-up; (2) It estimates the correlation between related measures and adjusts test statistics appropriately; (3) Time varying covariates can be incorporated into the model; and, (4) The assumptions about missing data are relaxed from Missing Completely at Random (MCAR) to Missing at Random (MAR).(77) The primary endpoint will be the estimated change from T1 to T2 in problem-solving skills and negative affect. The change from T1 to T3 will be considered a secondary endpoint. Because the outcomes of interest are correlated over time (p>.5), the power is increased relative to cross-sectional comparisons.

Exploratory Analyses

In addition to the primary analyses described above we will perform the usual descriptive analysis of the population, those who decline to participate and those who drop out of the intervention. We will also describe the use of the Website (e.g. number of times accessed, length of time on the site, most used features). We will examine models of mediation of treatment differences are observed in the outcomes. We will also examine selected demographic characteristics (maternal education, experience with the Internet) as moderators of the change over time associated with the two interventions.

Sample Size/ Power

Group sample sizes of 310 and 310 achieve 80% power to detect non-inferiority using a one-sided, two-sample t-test. The margin of equivalence (E) is -0.2 times the S.D. of the change from T1 to T2. We are assuming that effects of this size and smaller are not of practical significance. The significance level (alpha) of the test is 0.05. We estimated the sample size necessary based on our experience in previous trials. Estimates of the effect of PSST are obtained from the study of 429 mothers with the intervention delivered in English or Spanish using the same method of analysis as proposed for this study. Moderate effect (0.4 S.D.) was observed for the BDI and smaller effects (0.2-0.3 S.D.) for the POMS and problem-solving skills when compared to a no intervention control. Correlations between T1 and T2 assessments ranged from 0.5 to 0.7.

Interim Analysis: The proposed project is large and extends over 5 years. We plan to do an interim analysis at the point of 50% data collection to verify that the online approach is not inferior. Given our design parameters, the likelihood that this will necessitate study stoppage is extremely small. Should inferiority be demonstrated, we will stop study accrual, but will continue to complete interventions and follow-up assessments through T3 on all participants who have initiated the intervention. Based on the results of our prior trial, in which group differences were obscured at T2 by the effects of the shared supportive components of PSST and non-directive support, but the superiority of PSST emerged over time, it will be important to follow all participants to assess if equivalence becomes more apparent over time. If it is inferior, we will investigate cutting edge technology upgrades for the online intervention that have not been adequately tested or are cost prohibitive today in 2011.

Using a 1-sided t-test at a 0.05 level of significance, a fixed-sample trial would require a total sample size of 620 subjects (310 subjects in each arm) to have 80% power to detect a margin of equivalence of 0.2 standard deviations. The group sequential design in which an interim analysis is included requires a slight 1.3% increase in maximum sample size to 628 subjects (314 per arm). The interim analyses will be at equally-spaced in Information Time (i.e. after half of the subjects are enrolled and then again at the conclusion of the study if the study is not stopped at the interim analysis). At these two analyses, the stopping boundary to reject the null hypothesis the z-scores of 2.37 and 1.68, which results in Type I error spent at the analyses of 0.009 and 0.041 (for a cumulative total of 0.05).

Under the null hypothesis, the trial will likely go through both stages (expected stopping stage =1.99), with the average sample size (ASN) of 626 subjects. Under the alternative hypothesis, the expected stopping stage =1.73 and the ASN is 542 subjects, a 14% reduction in expected subjects from the fixed-sample design.

Aim 2: Qualitative Data Management

We will use the principles of constant comparative analysis of data(70) by coding and categorizing the interview transcripts through multiple readings by at least two independent researchers. A constant comparative method allows themes representing recurring patterns of behavior and meaning to emerge from the participants' own words. Through the use of "clustering" (grouping themes) and "metaphor making" (higher-order conceptual and figurative grouping),(78) existing and emergent possibilities and interfaces for diffusing this innovation will be strategically identified, and a dissemination plan created.

The constant comparative method for analysis is especially useful in generating "theories of process, sequence, and change which pertain to organizations, positions, and social interaction"(65) This method allows the continual gathering of qualitative data that confirms or disconfirms conceptual relationships - patterns and categories emerge and are confirmed or disconfirmed - helping the researcher determine the "why" of situations and thus boosting internal validity of the findings.(66) In so doing, the constant comparison method allows generalizability to be built up over time and across multiple studies.(65)

Building on the iterative constant comparative method, a dissemination plan for PSST will be established within the framework of *diffusion of innovations theory*. Diffusion theory invites researchers to analyze the processes through which particular innovations are developed, implemented, disseminated, and sustained in specific contexts and settings, and how such processes can be enhanced(49;50;79;80) When an intervention-study is designed with dissemination science in mind, the objective of internal validity is expanded to include external validity and diffusion.(81) For more information on diffusion of innovations theory see Appendix A.

FUTURE DIRECTIONS

The major goal of the current project is to develop an online PSST delivery system that is not inferior to the costly and labor intensive in-person Bright IDEAS paradigm of PSST that has been so well received and named to the National Registry of Evidence-based Programs and Practices (NREPP) as a Research-based Therapy/Intervention Program (RTIP). We are responding to our perfect score for Dissemination Capability, which compels us to find new ways to make the intervention accessible to family members of children with cancer anywhere the Internet is available, We believe that our ability to disseminate this intervention widely will play a crucial role in increasing the psychosocial support available to families even at cancer centers with very modest psychological resources. We further believe that the careful, multidimensional approach to program development and evaluation that we have put in place will allow us to combine user-centered/participatory research with the cutting edge theoretical framework of diffusion of innovations to formulate a prototype of generalizable dissemination principles. Formulation of these principles will have critical implications for how we can best use available and emerging technology to make our well-respected work a model of world-wide accessibility.

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