Report from a Multi-Institutional Randomized Clinical Trial Examining Computer-Assisted Problem-Solving Skills Training for English- and Spanish-Speaking Mothers of Children with Newly Diagnosed Cancer

Martha A. Askins,[1] PhD, Olle Jane Z. Sahler,[2] MD, Sandra A. Sherman,[3] PhD, Diane L. Fairclough,[4] DrPH, Robert W. Butler,[5] PhD, Ernest R. Katz,[6] PhD, Michael J. Dolgin,[7] PhD, James W. Varni,[8] PhD, Robert B. Noll,[9] PhD, and Sean Phipps,[10] PhD

[1]Department of Pediatrics, The University of Texas M. D. Anderson Cancer Center, [2]Golisano Children's Hospital at Strong, University of Rochester Medical Center, [3]Jonathan Jaques Children's Cancer Center of Miller Children's Hospital, Long Beach, [4]Colorado Health Outcomes Program, University of Colorado Health Sciences Center, [5]Department of Pediatric Hematology/Oncology, Oregon Health & Science University, [6]Department of Pediatrics and Psychology, Childrens Hospital Los Angeles, [7]Schneider Children's Medical Center, [8]Texas A & M University, [9]Department of Behavioral Medicine, Children's Hospital of Pittsburgh, and [10]Department of Behavioral Medicine, St. Jude Children's Research Hospital

Objectives To evaluate the feasibility and efficacy of a handheld personal digital assistant (PDA)-based supplement for maternal Problem-Solving Skills Training (PSST) and to explore Spanish-speaking mothers' experiences with it. **Methods** Mothers ($n = 197$) of children with newly diagnosed cancer were randomized to traditional PSST or PSST + PDA 8-week programs. Participants completed the Social Problem-Solving Inventory-Revised, Beck Depression Inventory-II, Profile of Mood States, and Impact of Event Scale-Revised pre-, post-treatment, and 3 months after completion of the intervention. Mothers also rated optimism, logic, and confidence in the intervention and technology. **Results** Both groups demonstrated significant positive change over time on all psychosocial measures. No between-group differences emerged. Despite technological ''glitches,'' mothers expressed moderately high optimism, appreciation for logic, and confidence in both interventions and rated the PDA-based program favorably. Technology appealed to all Spanish-speaking mothers, with younger mothers showing greater proficiency. **Conclusions** Well-designed, supported technology holds promise for enhancing psychological interventions.

Key words computer-assisted therapy; coping; mothers; e-health; pediatric cancer; problem-solving therapy; stress.

Among parents, the diagnosis and treatment of childhood cancer naturally constitute stressful experiences (Bonner, Hardy, Willard, & Hutchinson, 2007; Goldbeck, 2006). At the forefront of worries is the potential threat to their children's survival. Also of concern are the many logistical, family, and financial issues associated with care (McCaffrey, 2006; Mitchell, Clarke, & Sloper, 2006; Robinson, Gerhardt, Vannatta, & Noll, 2007). While considerable emotional resilience exists among parents, a sizeable percentage is at risk for developing anxiety and depression, especially during the initial months after diagnosis (Dolgin et al., 2007). Parental emotional well-being is important not only in and of itself, but also because of its close association with child's adjustment during the treatment (Robinson et al., 2007).

All correspondence concerning this article should be addressed to Martha A. Askins, PhD, Department of Pediatrics, Unit 87, The University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Blvd., Houston, TX, 77030-4009, USA. E-mail: maskins@mdanderson.org

Journal of Pediatric Psychology 34(5) pp. 551–563, 2009
doi:10.1093/jpepsy/jsn124
Advance Access publication December 17, 2008

Cognitive-behavioral therapy interventions have been shown to improve the psychosocial adjustment of parents of children with cancer (Kazak et al., 2004; Sahler et al., 2005). The Problem-Solving Skills Training (PSST) program, developed by Sahler and colleagues (Sahler et al., 2005; Varni et al., 1999), has been established as an effective intervention for enhancing problem-solving skills and decreasing negative affectivity (i.e., depression and anxiety) in mothers of children with newly diagnosed cancer. Support for a problem-solving approach is reinforced by the work of Norberg, Lindblad, and Boman (2005), who demonstrated that parents of children with cancer who use active problem-focused behaviors have less anxiety and depression than those with passive and avoidant reaction patterns.

PSST has been shown to be especially effective in Spanish-speaking Hispanic mothers (Sahler et al., 2005). This is an important finding considering that Hispanics constitute the fastest growing minority group in the United States and, as an underserved group, represent a National Institutes of Health priority. We theorize that PSST was especially beneficial for these mothers because the active problem-solving approach taught them a new set of skills and provided an alternative way of addressing problems, which in turn counteracted the greater feelings of helplessness and distress noted in this group (Sahler et al., 2005). Given that Spanish-speaking mothers who participated in the study had significantly fewer years of education, exposure to this educational approach to problem solving may have begun to address this deficit. Furthermore, PSST may have promoted acculturation in the medical setting in that a cognitive-behavioral style of approaching problems likely approximates the way in which treatment information is discussed with families in North American culture. It is also possible that meeting with a therapist filled an important cultural need for affiliation. Clearly, additional investigation regarding interventions for Hispanic mothers is merited to learn how best to address the needs of this growing population.

Traditionally, cognitive-behavioral interventions have been provided in the cancer outpatient clinic setting (Kazak et al., 2004; Sahler et al., 2005). Whereas these cognitive-behavioral models have helped create an excellent standard of care, providing such service in hospital settings is complicated by scheduling conflicts due to competing medical care priorities, financial costs of behavioral healthcare, and inadequate behavioral healthcare staffing (Mitchell et al., 2006; Orland, 1999). In addition, some parents prefer to focus on their own emotional health outside the hospital and clinic settings, for example, with an online computer support group. Therefore, it is important to create new, efficient methods of behavioral healthcare delivery that are effective, affordable, and comfortable for families while retaining the established efficacy of proven interventions. Computer technology is being explored as a means to enhance current psychotherapeutic interventions.

Because communications technology is becoming progressively more sophisticated, available, and affordable, innovative handheld, Internet-based, and computer-based technologies are being increasingly used in the delivery of behavioral healthcare (Taylor & Luce, 2003). The terms ''e-health'' and ''behavioral e-health'' have recently emerged and refer specifically to services that use Internet or computer-assisted strategies (Bischoff, 2004; Maheu & Gordon, 2000). These technologies are largely underresearched but have great potential to make psychological assessment and treatment more cost effective (Caspar, 2004). In addition, they are expected to improve access to specialty healthcare among underserved populations (Bischoff, 2004).

Therapeutic programs with computer-based components can be conceptualized along a continuum of professional therapy assistance (Jacobs et al., 2001) that ranges from stand-alone computer-based treatment without live therapist contact, to computer-based therapist-assisted treatment in which the computer is the primary treatment modality with the therapist assisting and responding to emergencies, to computer-assisted therapist-based treatment in which the therapist is central to the treatment. Jacobs et al. (2001) conducted a large, controlled clinical trial that compared a computer-based psychological treatment approach with traditional individual psychotherapy. The user explored a problem area and developed possible coping strategies with the option of implementing behavioral change. The results were favorable and comparable in both conditions, although traditional individual therapy out-performed computer-based therapy on some measures such as average amount of change ratings on at least one target complaint and client satisfaction. While emphasizing the importance of the therapist's role, these results also support the incorporation of computer intervention models in psychotherapy.

The present study examined the potential benefits of computer-assisted therapist-based training for mothers of children with newly diagnosed cancer. The study had three objectives: to evaluate the efficacy of the handheld computer supplement compared to traditional PSST; to evaluate the feasibility of implementing a computer-assisted PSST program on a personal digital assistant (PDA) platform;

and to explore qualitatively Spanish-speaking mothers' experiences with computer-assisted PSST. Specifically, it was hypothesized that mothers receiving PSST + PDA would demonstrate a greater decrease in negative affectivity than those receiving PSST alone. Note that the PDA was included in the present study as a supplemental resource to be used in conjunction with face-to-face PSST delivered by a therapist.

We chose the PDA as the technology platform because of its portability and convenience. PDAs have been used to collect behavioral data through electronic questionnaires (Zeman, Johnson, Arfken, Smith, & Opoku, 2006) and ecological momentary assessments (Rowan et al., 2007), but have not yet been widely incorporated into clinical practice (Taylor & Luce, 2003). The intervention was delivered through a computer program utilizing the PSST Bright IDEAS paradigm (Sahler et al., 2002). We theorized that presenting the five PSST cognitive-behavioral exercises (*I*dentify problem, *D*etermine options, *E*valuate options and choose best, *A*ct, and *S*ee if it worked) in an interactive, handheld computer format would make PSST more engaging and facilitate the acquisition of problem-solving skills beyond that afforded by the traditional therapist-only approach.

Methods

This study forms part of a larger randomized, controlled multi-institutional trial comparing the relative benefits of three psychological interventions for mothers of children with newly diagnosed cancer: traditional PSST; PSST with PDA; and a non-directive listening approach (control group). Because an interim analysis showed that there were no differences in outcomes between the first two conditions, the PSST + PDA arm was terminated early while the larger study continued. Thus, the current paper presents longitudinal quantitative comparisons between the traditional PSST and the PSST + PDA arms as well as qualitative data regarding participants' experience with the PDA. Institutional review board approval for the study was obtained at each participating site.

Participants

Participants were recruited 2–16 weeks after their child was diagnosed with any form of cancer at any of four pediatric cancer centers in the United States. Eligibility criteria included: ability to speak and read English or Spanish and permanent or temporary residence within a 50-mile radius of the participating cancer center (to maximize participation by taking transportation issues into account). To minimize burden, mothers were excluded from recruitment if their child was in severe medical crisis as determined by the oncologist. All eligible mothers of newly diagnosed pediatric patients were invited to participate in the study. A flow diagram of study progression is presented in Appendix A. Whereas reasons for withdrawal included the child's transfer to a different medical facility or death, reasons for dropout included a variety of other explanations, for example, unable to schedule sessions. Data collection and interventions were performed in both outpatient and inpatient meeting rooms.

Procedures

The interventions and assessments were delivered by therapists who had graduate training in psychology. The therapists were educated in PSST administration, PSST with PDA supplement, and non-directive listening in a group seminar lead by the research group's experienced investigators. Spanish-speaking therapists provided the interventions and assessments to Spanish-speaking mothers. Weekly supervision was provided to the therapists by the site principal investigators, all of whom were licensed psychologists.

Each potential participant received a written description of the intervention, associated goals, and the randomization procedure in an informed consent document. Upon completion of the baseline assessment, computerized randomization to one of the three treatment arms was performed at the data management center. Participants received a modest stipend to compensate them for their time.

PSST

The PSST intervention consisted of eight 1-h individual sessions conducted according to a comprehensive protocol (Varni et al., 1999; Sahler et al., 2002, 2005). Problem solving was presented as a general coping skill applicable to a range of challenging circumstances commonly encountered during the treatment of childhood cancer. To promote engagement, the specific problems discussed during the PSST intervention were identified by the individual mother as particularly relevant to her and her family's situation.

To facilitate learning the perspective and steps of PSST, the acronym ''Bright IDEAS'' was utilized with the logo of a lighted bulb (Sahler et al., 2002). *Bright* represents the sense of optimism (positive orientation) necessary for successful problem solving. The letters in ''IDEAS'' signify the five previously discussed major steps of problem solving (D'Zurilla & Nezu, 1990). Instructional material

included a treatment manual, a pocket-sized Bright IDEAS booklet for easy reference, worksheets for each step, trigger cartoons to help guard against negative automatic thoughts, and a Bright IDEAS refrigerator magnet. Details of the intervention were previously reported (Varni et al., 1999; Sahler et al., 2002, 2005). (Complete PSST intervention materials are available from Olle Jane Z. Sahler.)

The eight sessions of PSST flowed in a systematized, therapeutic manner. Session 1 was devoted to rapport building and understanding relevant social and medical information. In session 2, the therapist introduced PSST and the Bright ''IDEAS'' paradigm, presented worksheets to guide PSST homework assignments, and gave an overview of subsequent sessions. In sessions 3–7, the therapist and mother reviewed the mother's identified problems and the acquisition of problem-solving strategies and skills was promoted. Session 8 was dedicated to a review of the PSST training, emphasizing persistence and learned optimism, and the process of termination. Progress notes were recorded in a systematized format across intervention arms at all data collection sites and kept in each participant's study file.

PSST + PDA

This intervention consisted of the eight 1-h in-person sessions supplemented by a PDA device designed to provide: a brief review of the problem-solving process; review and practice of each of the five elements of the Bright IDEAS problem-solving approach; prompts to use problem-solving skills; and a periodic (e.g., daily) log to record problems confronted by the mother and her solutions. An explanation of Bright IDEAS by the animated character, Gina, as well as illustrations and worksheets were loaded into the computer program in both English and Spanish. The character Gina is part of an original interactive pedagogical drama designed specifically to train mothers in PSST delivered on a laptop (Marsella, 2002; Marsella, Johnson, & Labore, 2000, 2003). The computer programming to adapt Gina for delivery by PDA was performed by K. Barnes (Business Goals LLC, Salt Lake City, UT). Mothers were able to enter information by typing text, drawing a picture, or recording audio. PDAs were loaned to mothers for the duration of their participation to ensure accessibility. Unique user identification numbers were assigned to each PDA data set to protect confidentiality. Between sessions, subjects had unlimited access to this interactive, audiovisually enhanced computer program. The primary function of the PDA was to prompt adaptive cognitive-behavioral problem-solving practice. For example, prompts such as ''What is the problem?''; ''What are some alternative solutions?''; ''Try it out''; and then, at the next interaction, ''How did it work out?'' were asked. At this last prompt, the participant was encouraged to try other possible solutions from a menu of tailored strategies if she was less than fully satisfied with the results. Non-study-related functions were disabled on the PDAs. Auditing usage through weekly downloading of data by the therapist was planned to determine whether/how often the mother used the PDA for problem solving.

Beta testing of the new computer program on PDAs was conducted during the development phase of the project. Participants for the beta testing included mothers who had previously participated in PSST training, senior investigators, and research therapists. Feedback was given to the technologists, who in turn modified the PDA (e.g., added additional memory) or the computer program to enhance functionality.

For the PSST + PDA arm of the study, the traditional eight-session PSST delivery format was altered slightly. The general purpose and function of the PDA were presented in session 2 or 3. The therapist and mother worked through problems together on the PDA during sessions 3–7 to facilitate knowledge and skills acquisition. As with traditional PSST, mothers were asked to complete homework assignments consisting of working through their chosen problems using the ''Bright IDEAS'' paradigm. Homework completed during the previous week was reviewed in each session. Treatment integrity was ensured by audiotaping all sessions and randomly selecting 10% for review by senior members of the research team at sites that did not participate in data collection.

Measures

Demographic information about the children with cancer included age, gender, diagnosis, and time since diagnosis. Information about the mothers included age, education level, ethnicity, racial background, and marital status. After approximately one-third of the data had been collected, additional questions about participants' previous experience with computers and PDAs were added.

Assessments occurred at three time points: T1, baseline, prior to randomization; T2, immediately after completion of the intervention; and T3, three months after completion of the intervention. Outcome measures included the following problem-solving and psychological tests.

Social Problem-Solving Inventory-Revised (SPSI-R)

The SPSI-R (D'Zurilla & Nezu, 1990; D'Zurilla, Nezu, & Maydeu-Olivares, 1997) is a 52-item self-report linked to a

five-dimensional model of social problem solving. Respondents endorse statements by rating them on a five-point scale ranging from 1 (not at all true of me) to 5 (extremely true). The SPSI-R distinguishes between problem orientation, which, as an appraisal, can be positive or negative and three problem-solving dimensions (rational problem solving, impulsivity/carelessness style, and avoidance style). The sum of positive problem orientation and rational problem solving is termed constructive problem solving. The sum of negative problem orientation, impulsivity-carelessness style, and avoidance style is termed dysfunctional problem solving. The SPSI-R score (0–20) is the weighted average of the five subscores and constitutes the major outcome variable of focus in the present paper. A high total score indicates better problem-solving skills. The SPSI-R has been shown to maintain its factor structure following translation (e.g., Maydeu-Olivares, Rodriguez-Fornells, Gomez-Benito, & D'Zurilla, 2000; Siu & Shek, 2005). Internal consistency ratings in the current dataset were excellent with Cronbach's coefficient alpha values equaling .94, .95, and .95 across the three assessment time points.

Beck Depression Inventory-II (BDI-II)

This 21-item self-report assesses cognitive, affective, and behavioral components of depressive symptoms (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). Internal consistency ranges from 0.73 to 0.92, with good test–retest reliabilities cited in the test manual. The BDI-II has been used in studies assessing the relationship between problem-solving ability and depression. It included, in addition to the Profile of Mood States (POMS) scale, to investigate the replicability of previous findings. Internal consistency ratings in the current dataset were excellent with Cronbach's coefficient alpha values equaling .90, .93, and .93 across the three assessment time points.

Profile of Mood States (POMS)

The POMS (McNair, Lorr, & Droppleman, 1992) is a 65-item self-report that consists of a five-point objective rating scale about feelings over the previous week and measures six moods or affective states (tension or anxiety, depression or dejection, anger or hostility, vigor or activity, fatigue or inertia, and confusion or bewilderment). It is a sensitive indicator of change and demonstrates acceptable internal consistency, test–retest reliability, and validity. Internal reliabilities for the six subscales range from 0.84 to 0.95, and 6-week stability coefficients range from 0.65 to 0.74. The total mood state score was used in our analyses. Internal consistency ratings in the current dataset were excellent with Cronbach's coefficient alpha values equaling .96, .97, and .97 across the three assessment time points.

Impact of Event Scale-Revised (IES-R)

This 22-item self-report measure includes three subscales (intrusion, avoidance, and hyperarousal) that assess posttraumatic stress symptoms experienced during the preceding week in response to a specific event—in this case, the diagnosis of cancer (Weiss & Marmar, 1997). Internal consistency reliabilities of the intrusion, avoidance, and hyperarousal subscales are 0.91, 0.84, and 0.90, respectively. Internal consistency ratings in the current dataset were excellent with Cronbach's coefficient alpha values equaling .93, .95, and .94 across the three assessment time points.

Data Analysis

The data analysis for this paper was generated using SAS/STAT software, Version 9.2 of the SAS System for Windows (2006). Data from all participants were included in the analyses because we used an intent-to-treat statistical approach for the investigation.

Objective 1: Efficacy of Computer-assisted PSST in Comparison to Traditional PSST

The first objective was to develop, field test, and evaluate the computer program as a supplement to PSST, and compare this intervention to traditional delivery of PSST. A repeated-measures model examined the change over time of participants in the PSST and PSST + PDA arms by assessing both within- and between-group change on outcome variables. Maximum likelihood estimation for unbalanced (incomplete) repeated measures was used for all analyses (Jennrich & Schluchter, 1986). Rather than establishing a minimum number of sessions required for inclusion, all randomized participants were included in the intent-to-treat analyses. We estimated effect sizes for the changes from T1 (baseline) to T2 and from T1 to T3 using the standard deviation estimated from the baseline (T1) assessments for both within and between groups. Power to detect an effect size of 0.2 ranged from 0.2 to 0.7, and power to detect an effect size of 0.4 ranged from 0.6 to 1.0. Thus, in this sample, we had adequate power to detect a moderate effect.

Objective 2: Feasibility of Implementing a Computer-Assisted PSST Program on PDA

The second objective was to evaluate the feasibility of implementing a computer-assisted PSST program on a PDA platform for use by mothers of children with newly

diagnosed cancer. Spearman's correlation coefficients were computed to examine the associations between maternal age, years of education, and ethnicity with previous use of computers and PDAs. The associations between previous computer and PDA usage and outcomes on problem solving and the psychological measures within the PSST + PDA group were examined using Kendall's tau.

We asked several questions to help evaluate mothers' perceptions of the interventions immediately after sessions 1, 4, and 8 (or the last session in the case of early mastery or termination). The questions addressed mothers' perceptions of how logical the interventions seemed (i.e., did this seem like a valid, reasonable approach to helping them therapeutically), how optimistic mothers were that they would be successful with the intervention, and their confidence in the intervention. The mothers responded using a nine-point Likert-type scale (1 = not at all, 5 = somewhat, and 9 = very much).

The benefits and difficulties of using handheld technology were examined with a set of statements regarding the computer program and the PDA itself. Mothers responded along a four-point continuum of agreement, from ''strongly disagree'' to ''strongly agree.''

To track use of the PDA *in vivo*, we planned to perform downloads of data from the PDA to the central computer at each training session. Data to be downloaded included the number of times the mother accessed the program during the previous week, the number of times specific screens/panels were selected, the number of new problems listed, and their resolutions.

Objective 3: Qualitative Exploration of Spanish-Speaking Mothers' Experiences with Computer-Assisted PSST Technology

The third objective of our study was to learn more about the Spanish-speaking mothers' experiences using the PDA during PSST; thus, a qualitative analysis was undertaken at one of the data collection sites. The analysis consisted of reviewing the progress notes of the cohort of Spanish-speaking mothers, noting trends and recording themes pertinent to their comfort with both the PDA and the computer program.

Results

Recruitment and data collection began in September 2004. As an interim analysis showed no differences in outcomes between the traditional PSST and the PSST + PDA arm, data collection for the PSST + PDA arm was concluded in August, 2007, with the larger study still ongoing. At the time of the present analysis, 301 of the 524 (57%) eligible mothers had agreed to participate. The cohort for the present study included 197 participants (104 randomized to the PSST arm and 93 to the PSST + PDA arm). An additional 104 mothers were randomized to the time and attention control arm; however, data from these participants will be reported in a primary paper when the larger study is completed. There were no statistically significant differences in the demographic and medical characteristics of the participants in the two groups. The average age of participants was 36.3 years, with an average educational level of 12.7 years of schooling; their partners' average age was 39.2 years, with 13.4 years of education. The majority (72.5%) of participants had partners. Regarding race, 45.7% of mothers classified themselves as Caucasian; 39.6% as Hispanic; 7.6% as African American; and 7.1% as ''other.'' English-speaking mothers comprised 74.1% of the sample; the remaining 25.9% spoke primarily Spanish, and the intervention and all assessments were conducted in Spanish for these mothers. Mothers were enrolled in the study an average of 6 weeks after their child's diagnosis. The average age of the children was 8.1 years; 52.3% were boys and 47.7% girls. Diagnoses included leukemia (45.7%), non-neural solid tumors (14.7%), brain tumors (14.7%), and other (23.9%).

Objective 1: Efficacy of Computer-Assisted PSST in Comparison to Traditional PSST

Both the PSST and PSST + PDA groups demonstrated significant positive change over time on all measures, including improved problem-solving skills (SPSI-R), improved mood (POMS), reduction of depressive symptoms (BDI-II), and reduction of post-traumatic stress symptoms (IES-R), from both T1 to T2 and from T1 to T3 (Table 1). Contrary to the expectation that those in the PSST + PDA arm would show a greater decrease in negative affectivity, no differences were found between the two groups across time for any of the outcome measures.

Objective 2: Feasibility of Implementing a Computer-Assisted PSST Program on PDA

To evaluate interest versus burden of study participation, we reviewed the patterns of participation across treatment conditions. The average number of treatment sessions completed was four of the prescribed eight sessions, and no differences were found between the groups with regard to either number of sessions completed or frequencies of

Table 1. Estimates of Mean Change Over Time in Problem-Solving and Psychological Assessments for Participants in the Problem-Solving Skills Training (PSST) and PSST + Personal Digital Assistant (PDA) Study Arms

	Social problem-solving inventory-revised	Profiles of mood states	Beck depression inventory-II	Impact of events scale-revised
T2 & T1 change:				
PSST	1.2* (0.7–1.6)	−21.1* (–28.8 to –13.4)	−0.7* (–1.0 to –0.4)	−5.9* (–9.3 to –2.4)
PSST + PDA	1.3* (0.8–1.7)	−22.0* (–29.8 to –14.3)	−0.6* (–0.9 to –0.3)	−9.5* (–12.9 to –6.0)
Between-group differences for				
T2 & T1	0.1 (–0.5 to 0.8)	−0.9 (–11.6 to 9.7)	0.1 (–0.3 to 0.6)	−3.6 (–8.3 to 1.1)
T3 & T1 change:				
PSST	1.6* (1.1 to 2.1)	−30.9* (–39.5 to –22.3)	−1.3* (–1.6 to –0.9)	−11.4* (–14.7 to –8.0)
PSST + PDA	1.2* (0.6 to 1.7)	−30.1* (–38.8 to –21.3)	−1.1* (–1.4 to –0.7)	−13.7* (–17.1 to –10.2)
Between-group differences for				
T3 & T1	−0.4 (–1.1 to 0.3)	0.8 (–10.4 to 12.1)	0.2 (–0.2 to 0.7)	−2.3 (–6.8 to 2.2)

Note. 95% confidence intervals are provided in parentheses. T1: baseline, prior to randomization; T2: immediately after completion of the intervention; and T3: 3 months after completion of the intervention. An asterisk denotes statistically significant change ($p < .05$).

withdrawal and dropout (see Appendix A for flow diagram of study progression).

Additional analyses utilized the subset of participants ($n = 123$) who answered questions about prior experience with computers and PDAs. (As noted above, because these questions were introduced after the study began only two-thirds of the sample received these questions.) The analyses explored potential relationships between computer/PDA use, education, ethnicity, and the outcome variables. For computer use, 31.7% of participants said they had never used a computer, 16.3% used a computer less than 1 h/week, 18.7% used computers 1–3 h/week, and 33.3% used a computer more than 4 h/week. Regarding PDA use, 26.8% had never heard of the device, 52.9% had never used a PDA, 15.4% had previously tried a PDA but were not currently using one, and 4.9% used a PDA regularly. Spearman's correlation coefficients revealed that increased exposure to computers and PDAs was significantly associated with increased maternal age (computers $r = 0.22$, $p = .01$; PDA $r = 0.20$, $p = .03$) and years of education (computers $r = 0.65$, $p < .001$; PDA $r = 0.52$, $p < .001$). Less experience with computers/PDAs was associated with Hispanic ethnicity (computers $r = –0.49$, $p < .001$; PDA $r = –0.44$, $p < .001$). After accounting for years of education, maternal age was no longer significantly associated with computer/PDA use, while the negative correlation between Hispanic ethnicity and computer/PDA exposure remained significant (computers $r = –0.26$, $p < .01$; PDA $r = –0.25$, $p < .001$).

Correlational analyses using Kendall's tau statistic showed no significant associations between frequency of computer or PDA exposure and any of the study outcome variables for the subjects in the PSST + PDA group. Of note, since these analyses were confined to the PSST + PDA group, the sample sizes were relatively small, ranging from 45 to 48 participants.

To measure optimism, we asked mothers how successful they thought the intervention would be for them. Using a nine-point Likert scale, mothers in the PSST arm initially rated the potential success of this intervention as moderately high (mean = 7.6, SD 1.7). Likewise, mothers in the PSST + PDA arm endorsed positive expectations as moderately high (mean = 7.1, SD 1.4). However, differences between the groups were significant ($p < .05$). Midway through the interventions, mothers in the PSST arm expressed slightly more optimism than at baseline (mean = 8.0, SD 1.4), while ratings of mothers in the PSST + PDA arm remained the same (mean = 7.1, SD 1.8). The differences remained statistically significant ($p < .01$). These differences were no longer present by the third assessment time point, as expectations of benefit in the PSST + PDA group increased slightly (PSST mean = 7.9, SD 1.6; PSST + PDA mean = 7.6, SD 1.6).

Mothers were also asked to rate how logical the interventions seemed to them. Initially, mothers' ratings of logic in both arms were moderately high, with no significant differences between the groups (PSST mean = 7.8, SD 1.6; PSST + PDA mean = 7.4, SD 1.6). Midway through the interventions, the values remained similar, with no significant differences between groups (PSST mean = 7.9, SD 1.5; PSST + PDA mean = 7.3, SD 1.6). At completion of the intervention, the mothers rated the logic of the interventions at their highest levels, with no differences between the groups (PSST mean = 8.0, SD 1.5; PSST + PDA mean = 7.9, SD 1.4).

To measure confidence in the interventions, we examined whether mothers would recommend their particular

Table 2. Summary of Computer Program Evaluations by Participants

	Strongly disagree		Disagree		Agree		Strongly agree	
	N	%	*N*	%	*N*	%	*N*	%
Easy to use	1	2.1	14	29.8	21	44.7	11	23.4
Easy to keep	8	17.0	13	27.7	17	36.2	9	19.1
Keeping charged was not a problem	6	12.5	11	22.9	20	41.7	11	22.9
Text size was easy to see	1	2.1	5	10.6	25	53.2	16	34.0
Wording was easy to understand	1	2.1	7	14.6	23	47.9	17	35.4
Volume is comfortable	1	2.1	1	2.1	23	47.9	23	47.9
No problem understanding how organized	0	0.0	14	29.2	21	43.8	13	27.1
Gina helped me use the computer program	3	6.4	13	27.7	20	42.6	11	23.4
Gina helped me to apply Bright IDEAS	6	12.8	15	31.9	16	34.0	10	21.3
Gina helped me to feel better	9	19.1	14	29.8	14	29.8	10	21.3
Helpful to work with Gina	9	19.1	15	31.9	14	29.8	9	19.1
I liked working with Gina	5	11.1	13	28.9	16	35.6	11	24.4
Gina understood my problems	7	14.9	17	36.2	11	23.4	12	25.5
Ability to enter text was helpful	2	4.4	9	20.0	21	46.7	13	28.9
Voice recording was helpful	3	6.3	16	33.3	15	31.3	14	29.2
Easy to record	9	18.8	16	33.3	17	35.4	6	12.5
Ability to draw picture was helpful	8	17.8	16	35.6	18	40.0	3	6.7

intervention to other mothers of children with cancer. Initially, both groups endorsed a strong willingness to recommend their respective interventions (PSST mean = 8.0, SD 1.4; PSST + PDA mean = 7.7, SD 1.5) with no statistical differences between the groups. Midway through the interventions, the PSST arm was rated more favorably (mean = 8.6, SD 0.84), while the PSST + PDA arm was appraised slightly less favorably (mean = 7.3, SD 1.9), with the difference between the groups being statistically significant ($p < .001$). At completion, the willingness of the mothers in the PSST group to recommend the intervention remained at the same high level (mean = 8.6, SD 0.92). While still significantly lower than the PSST group ($p < .01$), ratings of mothers' willingness to recommend the PSST + PDA increased to its highest level (mean = 7.8, SD 1.6).

The benefits and difficulties involved with using the PDA were examined by asking mothers to rate their agreement with a set of statements regarding the computer program and the PDA itself. Mothers responded along a four-point continuum from ''strongly disagree'' to ''strongly agree'' (Table 2). Mothers endorsed that the computers were relatively easy to use and charge; however, only 55% thought that they were easy to keep (i.e., store and carry). Almost all indicated that they were very comfortable with the text size, wording, and volume of the audio recording feature. A majority, 71%, endorsed that the information contained in the program was organized and understandable. Overall, mothers endorsed a number of helpful aspects of the computer-animated facilitator (Gina), including directions for using the computer program, applying the Bright IDEAS paradigm, and even helping the participants ''feel better.'' A little over half liked working with Gina and felt she understood their problems. Although most mothers acknowledged these positive aspects of Gina, only half reported that it was helpful to work with Gina. Finally, entering text and audio recordings was helpful, but use of the voice recorder was problematic. The ability to draw pictures was not helpful for most.

One aspect of the feasibility of computer-assisted PSST was evaluating mothers' usage through weekly downloads. However, technical difficulties with the PDAs that could not be corrected rendered the data un-interpretable. These difficulties included: error messages in the computer program that resulted in periodic lost work; inconsistent recording of electronic data (e.g., date fields reset themselves automatically and incorrectly) that corrupted much of the stored data; and initially, PDA batteries losing their charge, resulting in lost data (this problem was corrected by adding a memory card).

Objective 3: Qualitative Exploration of Spanish-Speaking Mothers' Experience with Computer-Assisted PSST Technology

The total number of Spanish-speaking mothers who were randomized to the PDA arm across sites was 19. To better understand their experience with technology, therapy progress notes of the seven Hispanic mothers randomized to

PSST + PDA at one data collection site were qualitatively reviewed. In summary, the idea of using technology appealed to all of the Hispanic mothers randomized to this arm, regardless of age and education. Younger mothers showed great proficiency learning the program on the PDA and used the technology with great ease. All mothers chose not to focus on the PDA when their child was either in medical crisis or undergoing significant medical procedures (e.g., surgery). The one dropout and one withdrawal that occurred in this group appeared unrelated to randomization to the PDA arm because both occurred on or before the first session, which predates introduction of the PDA.

Discussion

In designing this study, we believed that the addition of the computer program would, at minimum, provide a helpful adjunct to the traditional PSST intervention, and, at best, enhance PSST and contribute to a computerized model of PSST so that in the future it could be provided with minimal therapist assistance and disseminated to a large group of mothers. In the process of developing and implementing the trial, we encountered multiple challenges but learned much that should be helpful to those interested in developing behavioral e-health programs. In addition, interesting cultural considerations emerged that will be relevant to computer programs targeted toward Hispanic populations and possibly other minority groups as well.

Outcomes in both the PSST and PSST + PDA arms of the study were comparable and favorable. Mothers in both groups enthusiastically endorsed high expectations of success, perceived the intervention as logical, and expressed a willingness to recommend their respective interventions. The PSST intervention, whether delivered in the traditional format or with the aid of the PDA, improved problem-solving skills among mothers of children with newly diagnosed cancer. In addition, mood improved and depressive and post-traumatic stress symptoms decreased over time. These results are consistent with the experience of Jacobs et al. (2001) who found similar positive outcomes for both traditional psychotherapy and computer-based therapy. The results are encouraging, despite the fact that the computer-assisted PSST approach did not appear to enhance the intervention. It is possible that the lack of difference between the groups is the result of a ceiling effect. Thus, it may have been difficult for the PSST + PDA arm to produce improvement beyond the range of close to normal functioning observed by the second and third assessment points. Nonetheless, the indistinguishable effect of adding the PDA raises several important points.

First, the PDA appears to be a good platform for presenting programs to improve the emotional and/or behavioral functioning of individuals in a healthcare setting. The PDA is small and portable and delivered educational information in a simple, bilingual format. The program incorporated a screen character (Gina) to make the program attractive and user friendly. Written, typed, and voice data entry by the user was permitted. The PDAs were cost effective in that they were less expensive than laptop or desktop computers and none were lost or stolen during the study. The majority of participants liked the various aspects of the PDA and computer program; however, a sizable minority did not. Thus, additional program development will be necessary in future iterations of computerized PSST.

A significant problem was that data could not be consistently and reliably transferred from the PDAs to computer data files for analysis as initially planned because of several irresolvable glitches. This was at times frustrating for therapists and participants, all of whom naturally wished to review work previously completed on the PDA, and to the investigators who wished to monitor usage. Zeman and colleagues (2006) documented similar technology problems in their efforts to implement a PDA platform to assess behavioral health in a primary care setting. These technical problems underscore the importance of not only having sufficient beta testing before launching a clinical trial, but also choosing a reliable partner in technology development. Significant time is required for program design, with multiple opportunities for pilot testing and redesign. Our group underestimated the time required for development, setting back recruitment more than 6 months. Small Business Innovation Research and Small Business Technology Transfer grants, sponsored by the National Institutes of Health, are available for technology development. Wisely, these grant opportunities are divided into two phases, with step-wise funding. Phase 1 is devoted to product development. Once a reliable product is developed, the investigator is eligible to apply for Phase 2 funding for efficacy studies. We suggest that, under the best circumstances, doubling the estimated time for development is closer to reality than any of us wish.

Second, several key components make a computer program successful. Aside from excellent content, an intuitive user interface, compelling presentation, and reliable, consistent, and useful functionality are critical. A user friendly and attractive product is much more likely to be

used regularly. Regular use is essential for delivering and reinforcing the intervention and attaining desired treatment goals. In the present study, the PDA and computer program received consistently high ratings, but the Gina character who talked the user through the problem-solving steps was rated positively by only about half the participants. Today, a myriad of audiovisual presentations are available to enhance computer programs. These include two- and three-dimensional animation, streaming video, interactive components, games, and synchronous (live chat and live video) and asynchronous (message boards and blogs) communication. It is possible that incorporating more of these ''bells and whistles'' would result in an improved therapeutic impact. Formal usability and focus group testing in future product iterations would help ensure high rates of user acceptance and compliance. This should include real-time testing with people from the target population.

Third, it is interesting to consider whether people who do not routinely use technology in their daily lives benefit from a technology-based behavioral intervention. In our study, we found that years of education was positively associated with computer use, and that Hispanic ethnicity was associated with less computer familiarity. Strikingly, in the present multi-institutional study, 31.7% of participants had never used a computer and an additional 16.3% used a computer less than 1 h/week. Even fewer were familiar with a PDA: only 15.4% had tried a PDA, and only 4.9% used one on a regular basis. Our analyses did not show differences in problem-solving or psychological outcomes based on participants' previous computer exposure or experience, a finding that has also been suggested in the literature (Zeman et al., 2006). Nonetheless, given our small sample size for this particular analysis and the general descriptive nature of the existing literature, more research is clearly needed.

Logically, it is reasonable to assume that computer-naïve adults may need more computer education before they can use this technology to enhance the intervention. Thus, building in additional time and training for those for whom technology is relatively new may not only be helpful in general but also improve the efficacy of the primary intervention and, hence, outcomes. Over the next decade, the computer information gap will shrink because of widespread integration of computer technology into educational curricula and the increasingly ubiquitous availability of personal computers and gaming systems that link to the Internet. Between now and then, however, it will remain essential to be prepared to provide additional instruction. Similarly, new technologies are constantly emerging and familiarity with one format or platform does not necessarily translate into familiarity with another.

Finally, this study was unique in including Spanish-speaking mothers and providing the intervention as well as all written and electronic materials in both English and Spanish. We know from previous studies of PSST that Hispanic mothers benefited the most from the intervention, probably for many reasons including the non-specific effects of affiliation and having a staff person interested in them and their problems. We also learned in the present study that Hispanic mothers had the least exposure to computer technology prior to entering the trial, thus raising potential questions about their proficiency and desire to engage in the PDA arm. We found, however, that Hispanic mothers were able to participate fully in all arms of the study and, moreover, that the idea of the PDA was very appealing to them. Not surprisingly, younger mothers became proficient more quickly and used the technology with great ease. Notably, none of the mothers chose to use the PDA when their child was in medical crisis, providing further insight into the applicability of this technology during different phases of treatment. Clearly, as has been known for a long time, it is easier to rely on the familiar when attention needs to be focused on serious and immediate health problems.

Challenges in computer technology development are inevitable given the rapid rate at which technology is advancing. Documenting our experience with the PSST computer program and PDA platform is intended to help others avoid similar pitfalls. New behavioral e-health programs offer great promise for making psychological interventions more accessible and affordable.

Acknowledgment

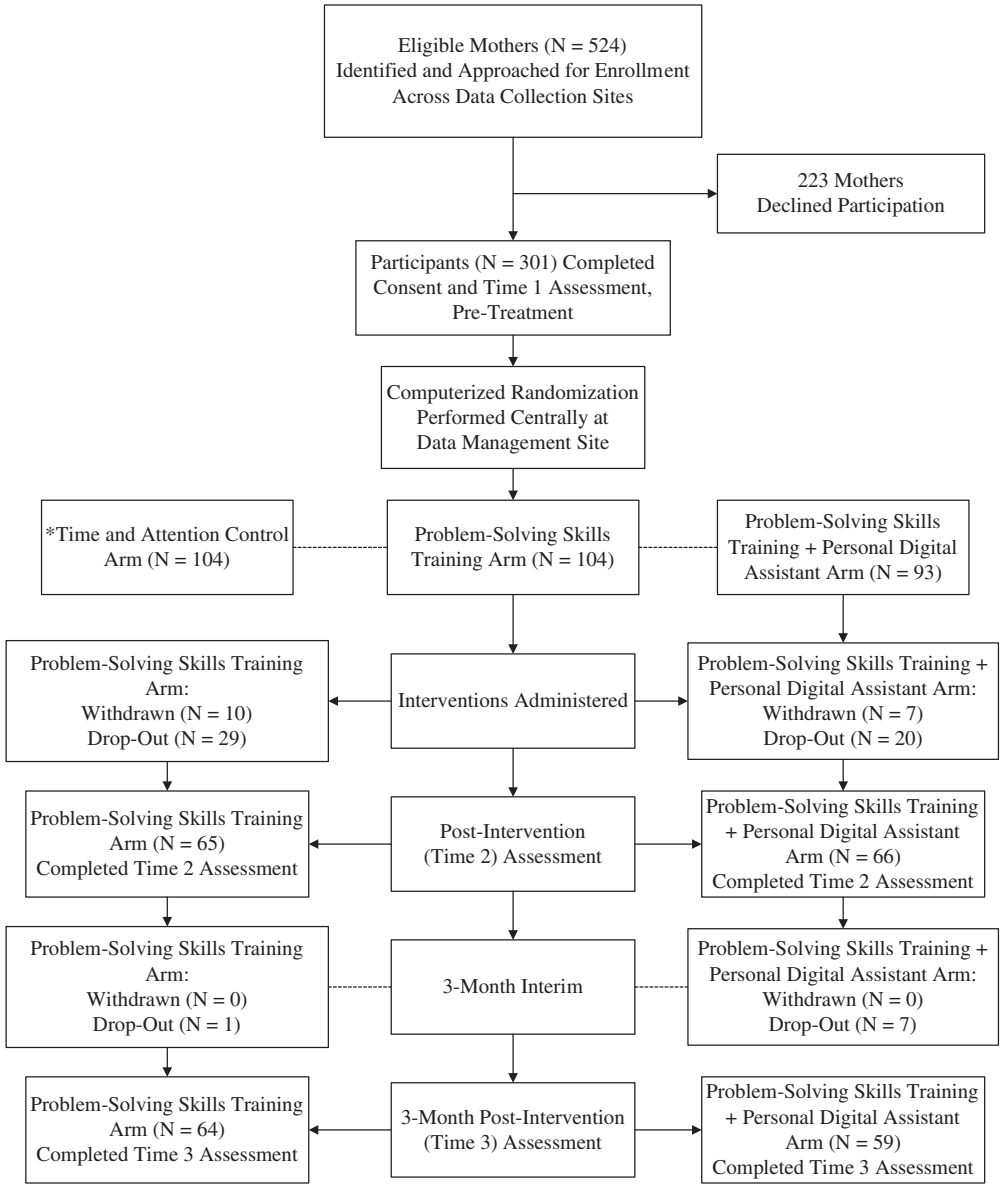
We wish to thank Sandra Medina-George, MS, for her dedicated work as a senior research assistant on the series of Problem-Solving Skills Training intervention studies and her expertise in Spanish language and multicultural considerations.

Funding

National Institutes of Health [grants CA 65520, CA 098954, and The University of Texas M. D. Anderson core grant CA 16672 for data management at this institution].

Conflict of interest: None declared.

Received October 31, 2008; revisions received and accepted November 3, 2008



*Note: Time and Attention Control Group was not included in the present data analysis.

Appendix A. Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram of Study Progression.

References

Beck, A. T., Ward, C. H., Mendelson, M., Mock, J., & Erbaugh, J. (1961). An inventory for measuring depression. *Archives of General Psychiatry, 4*, 561–571.

Bischoff, R. J. (2004). Considerations in the use of telecommunications as a primary treatment medium: The application of behavioral telehealth to marriage and family therapy. *The American Journal of Family Therapy, 60*, 173–187.

Bonner, M. J., Hardy, K. K., Willard, V. W., & Hutchinson, K. C. (2007). Brief report: psychosocial functioning of fathers as primary caregivers of pediatric oncology patients. *Journal of Pediatric Psychology, 32*, 851–856.

Caspar, F. (2004). Technological developments and applications in clinical psychology and psychotherapy: Introduction. *Journal of Clinical Psychology, 60*, 221–238.

Dolgin, M. J., Phipps, S., Fairclough, D. L., Sahler, O. J. Z., Askins, M., Noll, R. B., et al. (2007). Trajectories of adjustment in mothers of children with newly diagnosed cancer: A natural history investigation. *Journal of Pediatric Psychology, 32*, 771–782.

D'Zurilla, T.J., & Nezu, A. M. (1990). Development and preliminary evaluation of the social problem-solving inventory. *Psychological Assessment, 2*, 156–163.

D'Zurilla, T. J., Nezu, A. M., & Maydeu-Olivares, A. (1997). *Manual for the social problem-solving inventory revised (SPSI-R)*. North Tonawanda, NY: Multi-Health Systems.

Goldbeck, L. (2006). The impact of newly diagnosed chronic paediatric conditions on parental quality of life. *Quality of Life Research, 15*, 1121–1131.

Jacobs, M., Christensen, A., Huber, A., Snibe, J. R., Dolezal-Wood, S., & Potlterock, A. (2001). A comparison of computer-based versus traditional individual psychotherapy. *Professional Psychology Research and Practice, 32*, 92–96.

Jennrich, R. I., & Schluchter, M. D. (1986). Unbalanced repeated-measures models with structured covariance matrices. *Biometrics, 42*, 805–820.

Kazak, A. E., Alderfer, M. A., Streisand, R., Simms, S., Rourke, M. T., Barakat, L. P., et al. (2004). Treatment of posttraumatic stress symptoms in adolescent survivors of childhood cancer and their families: A randomized clinical trial. *Journal of Family Psychology, 18*, 493–504.

Maheu, M., & Gordon, B. L. (2000). Counseling and therapy on the Internet. *Professional Psychology Research and Practice, 31*, 484–489.

Marsella, S. (2002). Pedagogical soap. In K. Dautenhahn, A. Bond, L. Canamero, & B. Edmonds (Eds.), *Socially intelligent agents: Creating relationships with computers and robots* (pp. 141–148). Boston: Kluwer Academic Publishers.

Marsella, S., Johnson, W.L., & Labore, C. (2000). Interactive pedagogical drama. In *Proceedings of the Fourth International Conference on Autonomous Agents*, 301–308.

Marsella, S., Johnson, W. L., & Labore, C. (2003). Interactive pedagogical drama for health interventions. Paper presented at the International Conference on Artificial Intelligence in Education, Madrid, Spain.

Maydeu-Olivares, A., Rodriguez-Fornells, A., Gomez-Benito, J., & D'Zurilla, T.J. (2000). Psychometric properties of the Spanish adaptation of the SPSI-R. *Personality and Individual Differences, 29*, 699–708.

McCaffrey, C. (2006). Major stressors and their effects on the well-being of children with cancer. *Journal of Pediatric Nursing, 21*, 59–66.

McNair, D. M., Lorr, M., & Droppleman, L. F. (1992). *Manual for the profile of mood states*. San Diego, CA: Educational and Industrial Testing Service.

Mitchell, W., Clarke, S., & Sloper, P. (2006). Care and support needs of children and young people with cancer and their parents. *Psycho-oncology, 15*, 805–816.

Norberg, A. L., Lindblad, F., & Boman, K. K. (2005). Coping strategies in parents of children with cancer. *Social Science & Medicine, 60*, 965–975.

Orland, M. E. (1999). Financing more integrated children and family services: Current practice and opportunities for reform. *Journal of Educational & Psychological Consultation, 10*, 251–267.

Robinson, K. E., Gerhardt, C. A., Vannatta, K., & Noll, R. B. (2007). Parent and family factors associated with child adjustment to pediatric cancer. *Journal of Pediatric Psychology, 32*, 400–410.

Rowan, P. J., Cofta-Woerpel, L., Mazas, C. A., Vidrine, J. I., Reitzel, L. R., Cinciripini, P. M., et al. (2007). Evaluating reactivity to ecological momentary assessment during smoking cessation. *Experimental & Clinical Psychopharmacology, 15*, 382–389.

Sahler, O. J. Z., Fairclough, D. L., Phipps, S., Mulhern, R. K., Dolgin, M. J., Noll, R. B., et al. (2005). Using problem-solving skills training to reduce negative affectivity in mothers of children with newly diagnosed cancer: Report of a multisite randomized trial. *Journal of Consulting and Clinical Psychology, 73*, 272–283.

Sahler, O. J. Z., Varni, J. W., Fairclough, D. L., Butler, R. W., Noll, R. B., Dolgin, M. J., et al. (2002). Problem-solving skills training for mothers of children with newly diagnosed cancer: A randomized trial. *Journal of Developmental and Behavioral Pediatrics, 23*, 77–86.

SAS Institute Inc. (2006). *SAS ® 9.1.3 Procedures Guide*, (2nd ed.). Cary, NC, USA: SAS Institute Inc.

Siu, A.M., & Shek, D.T. (2005). The Chinese version of the SPSI-R: Some initial results on reliability and validity. *Journal of Clinical Psychology, 61*, 347–360.

Taylor, C. B., & Luce, K. H. (2003). Computer- and Internet-based psychotherapy interventions. *Current Directions in Psychological Science, 12*, 18–22.

Varni, J. W., Sahler, O. J. Z., Katz, E. R., Mulhern, R. K., Copeland, D. R., Noll, R. B., et al. (1999). Maternal problem-solving therapy in pediatric cancer. *Journal of Psychosocial Oncology, 16*, 41–71.

Weiss, D. S., & Marmar, C. R. (1997). The impact of event scale-revised. In J. P. Wilson, & T. M. Keane (Eds.), *Assessing psychological trauma and PTSD* (pp. 399–411). New York, NY: The Guilford Press.

Zeman, L. L., Johnson, D., Arfken, C., Smith, T., & Opoku, P. (2006). Lessons learned: Challenges implementing a personal digital assistant (PDA) to assess behavioral health in primary care. *Families, Systems, & Health, 24*, 286–298.