

Title: Pilot Testing eSCCIP: An eHealth Intervention for Parents of Children with Cancer

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Abstract

The psychosocial needs of children with cancer and their families are well-documented, as is the importance of providing interventions to support families throughout the cancer trajectory. The Surviving Cancer Competently Intervention Program (SCCIP and SCCIP-ND) is an in-person intervention for caregivers of children with cancer that uses principles from cognitive behavioral and family therapy to decrease anxiety and symptoms of posttraumatic stress and improve family functioning. Several studies have been published supporting SCCIP and SCCIP-ND as efficacious interventions. However, despite this evidence base, in-person interventions in pediatric psychosocial oncology have faced a number of challenges related to the numerous demands on patient and caregivers' time, difficulty of scheduling multiple treatment sessions, and high levels of stress in the context of cancer treatment. Interventions for non-English speakers are also limited.

In an effort to address many of these challenges, an eHealth adaption of SCCIP, called eSCCIP, has been developed. eSCCIP uses an innovative hybrid design (self-guided internet modules with brief telehealth follow-up) to deliver evidence-based skills and support to caregivers of children with cancer in an accessible and engaging format. The eSCCIP development process involved close collaboration with experts in internet intervention design and feedback from key stakeholders at all stages. The purpose of the proposed project is to: 1) Establish feasibility of eSCCIP through pilot testing with caregivers of children with cancer, 2) Establish preliminary efficacy of eSCCIP through pilot testing with caregivers of children with cancer. Preliminary efficacy will be shown by reductions in symptoms of acute distress, posttraumatic stress, and state anxiety, as well as improvements in family functioning, and 3) develop a Spanish language version of eSCCIP (eSCCIP-SP).

Emphasis will be placed on effect sizes and direction of mean differences from baseline to post-intervention. The next step in this line of research will be a larger grant to conduct a multisite randomized controlled trial of eSCCIP in English and Spanish.

1. Background

Survival rates for children with cancer have increased dramatically over the past 30 years due to medical advances (Ward et al., 2014). However, a cancer diagnosis and resultant treatment remains a stressful and often traumatic event for a family (Price et al., 2015). The psychosocial needs and risks of children with cancer and their families have been well documented in the literature (Kazak & Noll, 2015). The need for systematic interventions is also highlighted in the recently published psychosocial standards of care for children with cancer and their families (Weiner et al., 2015; Steele et al., 2015). Despite this, evidence suggests that the delivery of psychosocial care to children with cancer and their families is highly variable across treatment centers (Selove et al., 2012). Additionally, challenges exist regarding delivery of in-person interventions following a new diagnosis of pediatric cancer, including difficulties with retention and recruitment in research studies (Lutz Stehl et al., 2009). eHealth interventions, which use technology to enhance the delivery of psychosocial or medical care (Cushing & Steele, 2010; Palermo, 2008), present a unique opportunity to deliver an easily accessible intervention to families following a new diagnosis of pediatric cancer.

1.1 Introduction and Significance

The Surviving Cancer Competently Intervention Program (SCCIP) is a NREPP/RTIP listed intervention (R01CA63930) developed by Dr. Kazak that combines cognitive behavioral therapy and family therapy for families of children with cancer, with the broad goals of decreasing posttraumatic stress symptoms and increasing family functioning. The original SCCIP was a multifamily group intervention with adolescent survivors of cancer and their families. Pilot results found reductions in symptoms of PTSS and anxiety for adolescent cancer survivors and their parents (Kazak et al., 1999). Results from a larger RCT of 150 families suggest that the intervention was successful for decreasing symptoms of physiological arousal in survivors and intrusive thoughts for fathers, although families with higher levels of PTSS and distress were more likely to drop out before completing the intervention (Kazak et al., 2004). The second version of SCCIP (i.e., SCCIP-ND) was designed for use with individual families and geared towards caregivers of children newly diagnosed with cancer. SCCIP-ND is comprised of three intervention sessions for caregivers focused on identifying beliefs about cancer and its treatment, changing beliefs to enhance family functioning, and planning for the future (Kazak et al., 2005). The intervention also utilizes a unique multifamily video discussion group (MFVDG) that is incorporated into each session to help stimulate discussion. Through the MFVDG, SCCIPND participants meet and establish a connection to other caregivers who have similar experiences. The MFVDG was a highly innovative component of SCCIP-ND at the time of intervention development, utilizing a newer technology to introduce a standardized but personal family-systems component into the intervention. Evidence suggests that families found participation in SCCIP-ND to be acceptable and feasible right after diagnosis, although a larger RCT had numerous challenges, including difficulty of retaining families for a multi-session in-person intervention (Kazak et al., 2005; Lutz Stehl et al., 2009). Clinically, SCCIP-ND has been adapted for use with a range of

groups within the pediatric cancer community, including families of children with terminal diagnoses and families of children in remission, and is often referred to now as SCCIP.

Results from a mixed-methods study suggest that parents are amenable to the delivery of SCCIP-ND via technology, including interactive websites (Hocking et al., 2014). Broadly speaking, eHealth interventions use technology to enhance delivery of psychosocial or medical care, and may replace or supplement in-person intervention (Cushing & Steele, 2010; Palermo, 2008). Although the use of eHealth technology is growing and has great potential in terms of improving patient care and outcomes, it remains an understudied area in pediatric psychology (Palermo, 2008) and eHealth interventions are not widely available in pediatric cancer. Data indicates that 83.8% of households in the United States have access to a computer and 74.4% have internet access (File & Camille, 2014), indicating that web-based interventions have great promise in terms of supporting families who face barriers in terms of receiving face-to-face intervention services.

To this end, Dr. Canter has developed an eHealth adaptation of SCCIP-ND, called eSCCIP. This work was supported by an internal mentored research grant (Mentor: Anne Kazak, Ph.D., ABPP) from Nemours Biomedical Research titled "Implementation of Psychosocial Interventions in Pediatric Cancer: An eHealth Adaptation of the Surviving Cancer Competently Intervention Program (SCCIP)." The transformation of SCCIP into eSCCIP and eSCCIP-SP (a Spanish language version) represents a novel adaptation of an efficacious intervention to better serve a high-need population both in English and Spanish populations. In addition to hypothesized benefits related to accessibility and ease of use for individual participants, an online delivery mechanism is highly amenable to broad dissemination and increased reach. The development of eSCCIP and eSCCIP-SP is grounded in principles of participatory research and patient-centered care, with stakeholder (parents, psychosocial experts, physicians) involvement in all phases of project development and deployment. This represents an additional layer of innovation, as participatory research is an increasingly important factor in social and behavioral research that has not yet been fully integrated into the field of pediatric psychology.

1.2 Compliance statement

This study will be conducted in full accordance with all applicable Nemours Research Policies and Procedures and all applicable Federal and State laws and regulations. Any and all instances of noncompliance will be documented and reported to the Nemours IRB.

This study will be conducted in accordance with this protocol. Reporting of unanticipated events or problems involving risks to subjects or others will occur in accordance with Nemours IRB Policies and Procedures and all Federal requirements. Collection, storage, recording, and reporting of data will be secure, accurate and will ensure the privacy of research participants during and after the study.

2. Objective and Specific Aims

eSCCIP, an innovative eHealth intervention based on an efficacious intervention for caregivers of children with cancer (SCCIP-ND) has been developed as an accessible tool to provide critical psychosocial care to caregivers of children with cancer. eSCCIP is comprised of four online modules. Each module is comprised of a unique mix of original video content and interactive activities, and is complemented by a brief telehealth follow-up with an interventionist. After a rigorous development process, eSCCIP is ready to be pilot tested. This study will accomplish the following specific aims:

Specific Aim 1: Identify strategies for increasing participant engagement and retention by conducting focus groups or interviews with a diverse sample of parents of children with cancer (POCC) prior to pilot testing.

Hypothesis 1: Partnering with parents before initiating pilot testing will lead to the identification of strategies that can be implemented for successfully recruiting, engaging, and retaining participants.

Specific Aim 2: Demonstrate the feasibility of eSCCIP through testing with a diverse sample of POCC.

Hypothesis 2: 80% of POCC who participate in a pilot test of eSCCIP will endorse the intervention as acceptable, accessible, and feasible at post-intervention, comparable to acceptability data from SCCIP-ND.

Hypothesis 3: $\geq 45\%$ of eligible parents approached for participation will enroll in and complete a pilot test of eSCCIP, exceeding in-person participation rates for SCCIP and SCCIP-ND due to reduced participant burden.

Specific Aim 3: Evaluate preliminary effectiveness of eSCCIP through pilot testing with POCC.

Hypothesis 4: 80% of caregivers who participate in a pilot test of eSCCIP will report a reduction in symptoms of acute distress, posttraumatic stress, and anxiety from baseline to post-intervention.

Hypothesis 5: 80% of caregivers who participate in a pilot test of eSCCIP will report an improvement in family functioning from baseline to post-intervention.

Specific Aim 4: Develop a Spanish version of eSCCIP (eSCCIP-SP). Refer to Appendix for more details.

4.1: Determine the acceptability of the adaptation for key stakeholders.

This study fills a void in the psychosocial care of children with cancer and their families

by designing an adaptable and accessible eHealth intervention to support families through the cancer trajectory. The use of technology is novel and involving families in project development (i.e., prototype testing) and pilot testing is highly consistent with the Nemours True North mission. In addition to making psychosocial care accessible to a broader group of families, online intervention tools may be a cost effective approach to providing this care. This study will be an important first step in providing a critical service to families of children with cancer who only speak Spanish.

4.2 Evaluate effectiveness of the adaptation process

Spanish language interpreters at Nemours/AIDHC will be asked to complete an online evaluation form in order for the study team to collect qualitative feedback about the effectiveness of the adaptation process for eSCCIP-SP. The feedback will help provide useful information for future adaptation studies.

3. Research Design and Methods

3.1 Intervention Overview

eSCCIP is comprised of four online modules, with specific goals detailed below in Table 1. Each module is comprised of a unique mix of original video content and interactive activities, and is complemented by a brief telehealth follow-up with an interventionist. All video content was developed by Dr. Canter as part of her initial eSCCIP development grant.

Video content falls into two distinct categories: the Multifamily Video Discussion Group (MFVDG), which serves as a proxy of participants' interaction with other parents, and skillbuilding videos, where foundational intervention skills are introduced. The MFVDG is comprised of 17 parents (split into two smaller groups) who discuss their experiences with cancer. The MFVDG and is designed to capture themes common among caregivers of children with cancer (e.g., anger, guilt, emotional exhaustion), examples of coping (e.g. putting things in perspective, connecting with others, using humor as appropriate), and impact on the family over time (e.g., siblings, grandparents, thinking about the future). The five skill-building videos feature interviews with parents and providers, as well as graphics which illustrate foundational intervention skills (e.g., "footsteps to reframing").

Interactive activities provide opportunities for caregivers to practice the skills they have learned. All interactive activities are securely captured on the back end so that the interventionist can view all data that is entered by participants (e.g., text entered for free response questions, sequence of selections for drag and drop activities) and integrate participant responses into telehealth follow-up sessions. These telehealth follow-ups are the only component of the intervention that will need to be scheduled with an interventionist, lending a high degree of adaptability and flexibility to the overall program. The telehealth follow-up sessions will follow a flexible manualized format to ensure standardization across interventionists and appropriate follow-up about key intervention principles.

Table 1: Detailed Intervention Content

Module 0: Introduction to eSCCIP

The overarching purpose of Module 0 is to orient the family to the eSCCIP website and telehealth platform. The family will practice logging into the site and will review overall intervention goals. The family will be provided with a map of the intervention and will “meet” the families from the MFVDG. The family will also provide information about themselves to the interventionist through interactive activities.

Module 1: Identifying beliefs about cancer, its treatment, and the impact on the family

The overarching purpose of Module 1 is identify and discuss adversities and beliefs about cancer (e.g., cancer is an automatic death sentence, my family will never recover from this experience), as well as its impact on the family. The core skill introduced in Module 1 is the Adversity-Behavior-Consequence (A-B-C) Model. In addition to cognitive behavioral skills, the module also uses family systems theory to maintain an interpersonal focus and normalize the family’s experiences.

Module 2: Changing beliefs to enhance family functioning

The overarching purpose of Module 2 is to recognize and modify distressing beliefs which may lead to unwanted consequences. The core skill introduced in Module 2 is the Footsteps to Reframing. A particular focus is placed in beliefs and consequences that significantly impact family functioning and interpersonal relationships. The module uses principles from cognitive behavioral therapy to identify and modify beliefs and also uses family systems theory to maintain an interpersonal focus and prioritize concerns that impact family functioning.

Module 3: Creating a family survival roadmap

The overarching purpose of Module 3 is identifying and discussing beliefs about the future of the family, with a focus on growth. The module builds on previously introduced cognitive-behavioral skills (e.g., identifying beliefs about the present and future) and also uses family systems theory to maintain an interpersonal focus and help the family imagine a life after cancer treatment ends.

Telehealth Follow-Up Sessions

After each module is complete, participants will meet with their interventionist to review skills and discuss applications to their own lives. The telehealth follow-up will also facilitate engagement and joining with the family.

For the development of eSCCIP-SP, all current material on eSCCIP will be translated. Expert consultation and feedback from a panel of Spanish-speaking stakeholders will guide the development as eSCCIP-SP.

3.2 Participant Identification and Recruitment

3.2.1 Sample

Specific Aim 1 Sample: 10-20 caregivers of patients who are being treated for cancer in the Nemours Center for Cancer and Blood Disorders (NCCBD) at Nemours/A.I. duPont Hospital for Children will be recruited to participate in a focus group or interview targeting engagement and retention strategies. We will use purposive sampling to ensure that representation of women and ethnic and racial minority participants is proportional to our patient population (20% African-American, 5% Asian, 6% other; 16% Hispanic/Latino) and will also specifically recruit parents of children across age groups (i.e., infant, toddler, school age, adolescent) and diverse family structures (e.g., two caregiver households, single caregiver households). We will also ensure that parents of children with diverse

cancer diagnoses are represented, as well as a range of time since diagnosis. For the focus groups, individuals who may have more difficulty accessing an online tool due to financial or other barriers will be over-recruited to ensure that their perspectives are well-represented.

Specific Aims 2 and 3 Sample: This is a one-site pilot study at the Nemours/Alfred I. DuPont Hospital for Children in Wilmington, DE. A group of 23-30 caregivers will be recruited to participate in a pilot test of eSCCIP. This number was selected based upon a power analysis which indicates that 29 caregivers will be required to achieve power of .80 with an assumed .70 correlation, and 23 caregivers will be required to achieve power of .70 with an assumed .70 correlation. This sample is feasible based on the number of patients in active treatment currently followed by the Nemours Center for Cancer and Blood Disorders (approximately 200). Relationships with clinical staff (social workers, oncologists) in the Division of Oncology ensure that an adequate and representative group of participants will be easily recruited.

Dr. Canter will ensure that representation of ethnic and racial minority families is proportional to our patient population, and will also specifically recruit caregivers from major age groups (i.e., baby, toddler, school age, adolescent) and diverse family structures (e.g., two caregiver households, single caregiver households). Recruitment will be limited to caregivers of children who are on active treatment protocols (e.g., in treatment, receiving maintenance chemotherapy). Caregivers of children who have died will not be eligible for participation. While participation of both caregivers in two caregiver families will be encouraged, it is not an inclusion criterion. In order to ensure a representative sample, Dr. Canter will obtain a list of all patients who meet inclusion criteria in spring 2019. This list will be stratified by race, ethnicity, and age to ensure that the above-referenced parameters are met. After stratification, a random number generator will be used to randomly select participants for the pilot study.

Specific Aim 4: eight - ten Spanish-speaking caregivers of children with cancer will be recruited to participate in the MFVDG. Participants will be selected in consultation with psychosocial providers at N/AIDHC, and will also be considered members of the eSCCIP-SP family council. Purposeful sampling will be used to ensure adequate representation of diversity of cancer diagnoses (e.g., leukemia, solid tumors). Eligible caregivers will be approached in person or by phone about participation in the study by Spanish-speaking study personnel.

Aim 4.1: Think-Aloud Testing

Five Spanish-speaking caregivers of children with cancer will be asked to review the first version of eSCCIP-SP through a think-aloud testing session either in person or through a Nemours approved video chat platform. Purposeful sampling will be used to ensure adequate representation of diversity of cancer diagnoses (e.g., leukemia, solid tumors). Eligible caregivers will be approached in person or by phone about participation in the study by Spanish-speaking study personnel.

Think-Aloud testing is a widely used technique for collecting preliminary usability and feasibility data for eHealth interventions. Five Spanish-speaking families will be recruited to participate in Think-Aloud testing either in person or a Nemours approved through a video chat platform. In order to quickly identify any challenges and adapt the prototype as needed, the first three families who participate in Think-Aloud testing will be scheduled appointments to test eSCCIP-SP. Caregivers can choose whether they would like to review eSCCIP-SP in one study session or two shorter study sessions. Any changes that are deemed necessary after the review of each module will be made. This will allow for rapid responsiveness to participant feedback and quick refinement of the intervention.

After consent to participate is obtained, participants will be given a secure log-in and password to access the modules on the eSCCIP-SP website. For caregiver convenience, participants will have a choice to complete all Think-Aloud testing in-person at Nemours/Al DuPont Hospital for Children or complete testing virtually through a video chat platform. All Think-Aloud sessions will be recorded.

Aim 4.2: Interpreter Evaluation of the Adaptation Process

The Spanish language interpreters at Nemours/ AIDHC who aided in the development of eSCCIP-SP ($n=4$) will be asked to complete a brief online evaluation survey form. They will be asked to review the process of adapting eSCCIP into an online program for Spanish-speaking families. Their responses will be used to aid future adaptations.

While the study was pending grant review at NCI, a modified pilot was offered to families identified by psychosocial staff in the Nemours Center for Cancer and Blood Disorders. These families were not randomly selected, but were contacted by a member of the research team after identification by their primary clinical care team.

3.2.2 Recruitment

Specific Aim 1 Recruitment: Identified participants for focus group or interview testing will receive a letter or email (Appendix C) with preliminary information about eSCCIP and notification that they will be contacted within one week by a member of the research team. The Research Coordinator (RC) will then approach the parent during an in-person medical appointment or by phone to explain the purpose of the focus groups or interviews, discuss informed consent, and, if interested, schedule the participant for focus group or interview participation. If unexpected challenges arise related to focus group or interview recruitment, we will work with multidisciplinary team members in the NCCBD to identify additional eligible participants and reach out to explain the purpose of the focus groups. Study staff regularly attend Oncology Psychosocial Rounds, where multidisciplinary team members discuss patients being treated in the NCCBD, including newly diagnosed patients. These meetings are an additional opportunity to address recruitment barriers and generate solutions.

Specific Aims 2 and 3 Recruitment: Identified participants will be mailed a letter (Appendix D) and flyer (Appendix E) to introduce the study and

eSCCIP. Potential participants will have the opportunity to contact us if they are interested in participating, but they will also be notified that we will contact them by phone within a week of receiving the letter and flyer. During the phone call, the RC will explain the study and go over the informed consent form with the participant. All participants will have the opportunity to ask questions during the phone call with the RC.

Potential participants for this study will be caregivers of children with cancer and it might be difficult for them to complete consent and baseline measures during their child's treatment appointment. For the participant's convenience, we will have the option of completing consent and baseline measures electronically.

There will be a verbal interaction between a research coordinator and all participants to review the consent prior to the participant signing e-consent. The RC will give the participant the option of signing up for the study right after the interaction or they may take some time to think about the study before signing up. If the participant needs more time to decide, they will be given a link to review and sign the consent electronically at a time of their convenience. This will give participants plenty of time to decide if they want to participate in the study. If the participant is ready to sign consent at the time of their appointment, the RC will collect the electronic consent in-person using a tablet.

Prior to signing the electronic consent, potential participants will also be provided with the phone numbers and email addresses of the RCs just in case they would like to speak to a study team member again. This will give the participants the opportunity to ask additional questions after the initial interaction with the RC but before signing the consent form.

Electronic Informed consent will be obtained through the REDCap system. REDCap supports two secure, web-based applications designed exclusively to support data capture for research studies. Mechanisms are in place to assure that data is stored securely. REDCap uses an e-consent framework to allow consenting research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. When the participant electronically signs the consent form, an extra certification page is added displays an in-line PDF copy of their responses in which they will be asked to confirm that all the information in the document is correct. The RC obtaining consent will sign and date the consent. Upon the completion of the consent form, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's file repository. A copy signed by the participant and the RC will be sent to the participant via email for their records.

We expect the vast majority of participants will choose the electronic consent process, however we will also offer the option of reviewing and signing a paper copy of the consent form. The participant and the RC will sign electronically using their computer mouse or finger. Participants will receive

a copy of their signed informed consent form via email (or hard copy if they sign a paper copy). Paper copies will be kept in a locked file cabinet inside of the PI's personal office, which is locked whenever the PI is not present. The informed consent process will be documented in the participant's research record

The RC will orient the family to the RedCap data capture system (more detail provided in Data Management subsection), the eSCCIP website, and the telehealth follow-up platform. After obtaining informed consent, the family will create a timeline for intervention completion with the RC. Ideally, they will complete one module with telehealth follow-up per week. The RC will also inform the family that post-intervention measures will be sent via RedCap email following intervention completion, and that they will be contacted by the RC when measures are sent.

Specific Aim 4: Eligible caregivers will be sent a recruitment email (Appendix F) and then approached in person or by phone about participation in the study by study personnel. The RC will explain the study and then work with the potential participants to schedule a date for the MFVDG. Informed consent will be obtained on the day of the MFVDG.

Aim 4.1: Eligible caregivers will be approached in person or by phone about participation in the study by study personnel. The RC will explain the study and then work with the potential participants to schedule some dates to test the Spanish version of eSCCIP. eConsent procedures (as highlighted in section 3.2.2, *Specific Aims 2 and 3*) will be used to obtain consent of all participants. The option to review and sign a paper consent will also be available.

Aim 4.2: Interpreters will receive an email from the study team with the link to the survey. They will be sent weekly email reminders for three weeks until they complete the survey. Consent for interpreters will be waived in order to keep their identities anonymous (see Waiver of Documentation).

3.2.3 Participant Incentives (Appendix G)

Specific Aim 1 Incentives: Each participant will receive a \$30 gift card.

Specific Aims 2 and 3 Incentives: All participants in the randomized pilot test will be given a \$50 debit card after the completion of post-intervention measures. Gift cards will be delivered in person or mailed. If mailed, the participant will be asked to contact the RC to confirm debit card receipt before the debit card is activated. Participants in the modified pilot test (while pending grant review) received a \$50 debit card. Funding was provided through Dr. Anne Kazak's ACCEL grant mentor funds.

Specific Aim 4 Incentives: All participants that participate in the MFVDG will be given a \$100 debit card after the discussion is done. Funding was provided by the Center for Pediatric Traumatic Stress (CPTS).

Aim 4.1: All participants that participate in the Think-Aloud testing of the Spanish version of eSCCIP will receive a \$75 debit card once they complete all the modules. Funding is provided by the Mattie Miracle Foundation.

Aim 4.2: In order to keep participation of the Spanish language interpreters completely anonymous, we will not collect any personal information, therefore they will not receive payment for their participation.

4. Intervention Delivery and Data Collection

4.1 Measures

For Specific Aim 1, semi-structured guides will be developed for the focus group or interview sessions (Appendix H, I) to gather participants' perspectives about strategies to increase engagement and retention. For example, participants will be prompted to discuss substantive and logistical barriers to participation, challenges to maintaining interest, and communication strategies that could be implemented to sustain engagement. Specific questions about engaging participants who are more distressed or endorse symptoms of PTSS will be included, as well questions about any exclusion criteria that should be implemented based on time since diagnosis. The discussions will be audio taped and transcribed.

For Specific Aims 2 and 3. The family will be encouraged to complete baseline measures at the time of recruitment, but will be given the option to complete using a secure web-link at a later time. Following completion of baseline measures, the family will login to the eSCCIP platform and complete Module 0 with subsequent telehealth follow-up, per the timeline determined at the time of recruitment. After completion of one module, the next module will be released through the online delivery platform. New modules will be released one at a time until the family has completed the full intervention, at which point post-intervention measures will be sent electronically via RedCap. Dr. Lee Ritterband, expert eHealth consultant, will provide consultation throughout intervention delivery to share insight regarding best practices and help manage any unanticipated difficulties. The second interventionist, Dr. Aimee Hildenbrand, is a postdoctoral fellow with experience in psychosocial oncology and medical traumatic stress. Dr. Hildenbrand will be trained in the delivery of eSCCIP prior to study initiation, and will also be trained in the delivery of the in-person SCCIP. Dr. Hildenbrand and any additional interventionists who join the study team will receive regular supervision from Dr. Canter over the course of the grant. A manual has been developed by Drs. Canter and Kazak to ensure that all participants receive standardized follow-up telehealth care(Appendix J, K, L). A fidelity checklist has also been developed by Drs. Canter and Kazak to monitor fidelity and intervention adherence for the telehealth follow-up sessions (Appendix M). A subset of telehealth follow-up sessions will be audio recorded and transcribed to allow for fidelity checks. The fidelity checks will

only be conducted on newly enrolled participants (not participants already enrolled in the pilot study).

Telehealth appointment reminders will be sent by the RC prior to each scheduled session. Appointment reminders will be sent via the participant's preferred mode of communication (phone, email, or text message).

In the modified pilot test, all baseline and post-intervention measures were completed using paper forms during previously scheduled outpatient or inpatient visits/admissions. All other study procedures will be the same.4.1 Measures

Consistent with Specific Aim 2, data will be collected on acceptability, accessibility, and feasibility of the intervention at post-intervention only. Caregivers will rate eSCCIP using the eSCCIP Evaluation Questionnaire and the Internet Intervention Adherence Questionnaire, which have been used in previous eSCCIP work and was developed based on similar questionnaires used by leaders in the field of eHealth intervention development,.

Consistent with Specific Aim 3, data will be collected on symptoms of posttraumatic stress, acute distress, state anxiety, and family functioning at baseline and post-intervention. The PTSD Checklist for DSM-5 (PCL-5) is a 20-item self-report measure that will be used to assess for symptoms of PTSD. The National Comprehensive Cancer Network Distress Thermometer (DT) and Problem List is a single-item indicator of psychosocial distress that is widely used in the oncology literature. The SCORE-15 is a 15-item self-report measure of family functioning and relationships that is sensitive to change over the course of a psychosocial intervention. The Generalized Anxiety Disorder 7-Item Scale (GAD-7) is a 7-item self-report measure of symptoms of generalized anxiety. The COVID-19 Exposure and Family Impact Survey (CEFIS) is a caregiver-report measure of the extent to which family members have been exposed to potentially traumatic aspects of the COVID-19 pandemic and the degree to which this exposure is perceived as challenging or beneficial. CEFIS has two scales. CEFIS was developed in rapid response to the unfolding impact of COVID-19 on families around the world.

Demographic information will also be collected at baseline using the Psychosocial Assessment Tool (PAT) and a review of the electronic medical record. In addition to demographic information, the PAT will be used to assess family areas of risk and resiliency in multiple domains. Participants will be encouraged to complete all data using RedCap, but paper forms will be available as well.

For Specific Aim 4, a conversation guide will be created to facilitate the Spanish-language MFVDG.

For Aim 4.1, The Think-Aloud process is a data-generating process. Participants will be instructed to "Think-Aloud" about their experience using and interacting with eSCCIP-SP. All utterances will be audio-recorded and any questions or comments will also be transcribed by study personnel. These narratives will be used to edit and refine the eSCCIP-SP modules iteratively, with each set of changes from one module also being incorporated into the other modules. Participants will be compensated for their time and efforts.

For Aim 4.2. Interpreters will be asked to complete a brief online evaluation form (Appendix N) on REDCap. The link to the form will be emailed to all interpreters.

4.2 Data Management

All data will be collected, managed, and stored using the research-focused electronic data capture system REDCap. REDCap supports two secure, web-based applications designed exclusively to support data capture for research studies. Mechanisms are in place to assure that the de-identified data is stored securely. Any data that is collected via paper form will be entered into RedCap by study personnel. Any paper surveys will be stored securely and de-identified, consistent with study procedures for storing other hard copy data. An “entered by” field will be included in RedCap for accurate tracking of data entry.

All data in the modified pilot will be entered into a password protected Excel file, accessible only to the PI and Research Coordinator. This data will also be entered into REDCap for security and data management purposes. Paper forms will be stored securely, consistent with study procedures for storing hard copy source material.

The MFVDG video will be stored on the Nemours secure server, consistent with procedures utilized during development of the English-language eSCCIP.

5. Data Analysis

Specific Aim 1 Data Analysis: Demographic information (Appendix O) will be collected from all participants in the focus groups and interviews. Transcribed focus group and interview data will be coded by study team members with guidance from Dr. Janet Deatruck, expert qualitative consultant. Directed content analysis will be conducted, using a priori codes generated by the study team and additional codes identified in ongoing transcript review. After the coding structure becomes established, two coders will independently code a subset of the transcripts to examine consistency in coding under the supervision of Dr. Deatruck. Discrepancies will be resolved by consensus among the investigators. In order to strengthen the rigor of the analysis, a primary and secondary coder will be assigned as analysis continues with the secondary coder checking the coding of the primary coder as well as completing a summary of data on each category within that case (group) and across all cases (groups). The case summaries and samples of the coding process will be reviewed in regular meetings of the study team. Through this process, codes will be transformed into categories, and categories into themes that explain strategies for engaging research subjects, minimizing attrition, and keeping participants engaged for the duration of the study.

Specific Aims 2 and 3 Data Analysis: Data will be analyzed by Dr. Canter with support from the Senior Biostatistician in the Nemours Center for Healthcare Delivery Science. Dr. Lee Ritterband, expert eHealth consultant, will provide additional consultation regarding the analysis and interpretation of acceptability,

utility, and feasibility data. A more detailed analytic plan is organized below by hypothesis.

Hypothesis 2: The eSCCIP Evaluation Questionnaire and Internet Intervention Adherence Questionnaire (IIAQ) will be scored and reliability will be computed using Cronbach's alpha. Mean scores and distributions will be computed and used to determine acceptability, utility, and accessibility of the intervention for caregiver participants (e.g., higher mean scores will represent more favorable impressions of eSCCIP). The eSCCIP Evaluation Questionnaire consists of 21 questions rated on a five-point Likert scale (0 - 4). For the purposes of evaluating Hypothesis 2, responses of 3 ("mostly true") and 4 ("very true") will be used to indicate endorsement of the acceptability and utility of eSCCIP. A total measure score ≥ 63 (i.e., the value obtained if a participant selected "mostly true" for all items) will indicate that a participant found the intervention acceptable and useful. The IIAQ will be utilized to assess participant impressions of intervention accessibility. The IIAQ consists of 16 questions rated on a four-point Likert scale (0 - 3). Responses of 0 ("not a problem") and 1 ("a little problem") will be used to indicate good intervention accessibility in our sample. A total measure score ≤ 16 (i.e., the value obtained if a participant selected "a little problem" for all items) will indicate that a participant found the intervention accessible. The selection of values indicating endorsement of eSCCIP was guided by past work involving the evaluation of eHealth interventions using similar measures.

Hypothesis 3: Descriptive statistics will also be computed and used to evaluate Hypothesis 3 (e.g., proportion of eligible participants enrolled, eSCCIP module completion, telehealth attendance, telehealth reschedule data, retention for enrolled participants).

Hypotheses 4 and 5: The PCL-5, Distress Thermometer, GAD-7, and SCORE-15 will be scored and reliability will be computed using Cronbach's alpha. Descriptive statistics, including mean scores and distributions, will be computed for all measures and assumptions underlying statistical procedure will be checked. Items on the PCL-5 are rated on a 5-point Likert scale ("Not at All" – "Extremely"), with an overall cut-off score of 33 suggested for clinical impairment until full psychometric data is available for the measure. Based on psychometric evidence from the PCL-5 for DSM-IV, a change of 5-10 points suggests reliable change and a change of 10-20 points suggests clinically significant change. The DT is a single-item screener ranging from 0 – 10 ("No Distress" – "Extreme Distress") with several Yes/No items describing different areas of difficulty. Items on the SCORE-15 are scored on a 5-point Likert scale ("Not at All" – "Very Well"). An overall score is generated, as well as three subscales: Strengths and Adaptability, Overwhelmed by Difficulties, and Disrupted Communication, with high scores suggesting more impairment. Items on the GAD-7 rated on a 4-point Likert scale ("Not At All" – "Nearly Every Day") with higher scores indicating greater anxiety. Guidelines for interpretation indicate that a score of ≥ 10 suggests a possible diagnosis of Generalized Anxiety Disorder. CEFIS has two scales. The Exposure scale consists of 25 items that are answered as Yes/No with a total score of 0 to 25. The Impact scale consists of 12 items, 10 of which use a 4 point scale and 2 with a 10 point scale. The total score can range from 12 to 60. Higher scores denote more exposure and more (negative) impact.

All outcome data will be analyzed using paired sample t-tests. Because this is a pilot study, emphasis will be placed on effect sizes and associated confidence intervals over statistical significance. Mean differences and direction of effects will also be reviewed. All effect sizes will be computed using Cohen's *d* and interpreted using accepted guidelines for small, medium, and large effects.

6. Human Subjects Protection

We will rely on Nemours Office of Human Subjects Protection (OHSP) policies and procedures to guide all aspects of our study design and implementation. The attached consent documents will be reviewed by the Nemours OHSP Institutional Review Board before study initiation.

Study procedures for the development of eSCCIP have been previously approved by the Nemours IRB, and similar procedures will be utilized to protect participant data. This is a minimal risk study. This is a caregiver-only intervention, and no minors will participate directly in the study. Informed consent (electronic or paper copy) will be obtained prior to participation, as will an institutional telehealth consent form. Eligible participants will be approached in-person or by telephone by study personnel. The website used to access eSCCIP is housed within Nemours Biomedical Research and is secure for research. Participants will be assigned a unique log-in and password prior to completion to ensure that no identifiable information is entered. The telehealth platform is encrypted and secured, and is used across our institution for clinical and research telemedicine delivery. A medical chart review will also be completed for the children of eligible participants. REDCap, described in more detail above, is used across our institution for research. All paper study related documentation will be kept in a locked file cabinet inside of the PI's personal office, which is locked whenever the PI is not present. All data will be identified only by Subject ID and the master list linking participants to unique Subject IDs will be kept separately from the rest of the study data.

The PI for this grant is a licensed psychologist and is able to triage and address clinical concerns that may be identified from the study. An after-hours number will be provided for the staff on-call psychologist in the unlikely event that immediate psychosocial care is needed outside of normal business hours. Technological support will be available during business hours to manage any web concerns. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including serious adverse events) these will be reported to the sites IRB in accordance with accepted policies.

6.1 Risk Assessment

The research activities for this study present no more than minimal risk to participants. Because of the interventionist follow-up after each module, any emotional distress will be readily identified and referrals will be provided in the unlikely event that safety concerns are apparent. Because Dr. Canter will be conducting the telehealth follow-up, she will not be responsible for enrolling or consenting participants for the study. She will also not be

responsible for administering any pre- or post-intervention measures. These steps will eliminate the possibility of bias due to a dual role.

In the MFVDG, participants will be asked to discuss their child’s cancer, their reactions to the cancer, and their family; this may be potentially upsetting for some people. Caregivers have the option to skip any portion of the discussion that they do not wish to participate in. Caregivers can also request to be removed from the filmed MFVDG prior to final video editing.

6.2 Potential Benefit

This study is an adaptation of an intervention for caregivers of children with cancer, and many caregivers find participation in this intervention to be helpful and valuable. The knowledge gained from this research may also help us provide better care and support to other families in the future.

6.3 Safety Monitoring Plan

As this study poses no more than minimal risks to participants, the Principal Investigator will monitor study progress, ensure the accuracy and security of the data and ensure subject safety.

With that said, there are six items in the study battery that may be particularly salient clinically (Red Flag items) in Aim 2 and 3 of the study. The Red Flags are classified as High Risk and Standard Risk (see below; High Risk Red Flag items are bolded). High Risk items relate to suicidality and may indicate the need for immediate attention and further evaluation. Standard Risk items indicate that the participant may be experiencing some distress, but the situation is not emergent.

| Red Flag Items | | |
|--|---|---|
| Item | Measure | Answer endorsed to appear on “red flag” report |
| Talk about suicide / has made a suicidal attempt (HIGH RISK item) | PAT: Does your child... | Sometimes OR Yes |
| Talk about suicide / has made a suicidal attempt (HIGH RISK item) | PAT: Do any other children in your home... | Yes |
| Has anyone talked about or attempted suicide (HIGH RISK item) | PAT: About the adults (caregivers) in the child’s home | Yes |

| | | |
|---|--|-----------|
| Is anyone really sick or have a serious medical problem | PAT: About the adults (caregivers) in the child's home | Yes |
| Distress thermometer | Distress thermometer | 9 or 10 |
| Feeling distant or cut off from other people | PCL-C | Extremely |

In order to identify endorsed Red Flag items, the RC will review the Red Flag items in person (for modified pilot) or in REDCap after the completion of data collection and while the participant is present. If a participant completes the study battery remotely or without the RC present, a system-generated automated email will be sent to the RC if a Red Flag item is endorsed.

If any Red Flag items are endorsed or if a participant appears to be in acute distress, the RC will ask the participant to confirm his/her answers and ask for additional information to determine whether there is an imminent risk for harm to the participant or a member of his/her family. If a participant completes the questionnaires remotely, the RC will assess this information via telephone immediately upon noting the endorsement.

If the participant reports that the Red Flag item is a past concern and/or is actively being resolved (e.g., through work with a member of the clinical care team), the RC will report the Red Flag endorsement to the PI. The PI, who is a licensed clinical psychologist, will determine whether any action needs to be taken beyond documenting the endorsement. If needed, the PI will follow-up about these items during the next scheduled telehealth session with the participant.

If the participant reports that the Red Flag item is a current concern and/or is not being adequately resolved, the RC will remain with the participant (if in person) and immediately contact the PI. The PI or RC will notify a member of the clinical care team (LCSW or embedded psychologist) and explain the situation in person, by email, or by telephone. Plan of action will be determined by the clinical care team in coordination with the PI, dependent upon participant needs and level of concern. Endorsement will be documented, and a follow-up email will be sent to the clinical care team that summarizes the determined plan of action. If needed, the PI will follow-up about these items during the next scheduled telehealth session with the participant.

6.4 Confidentiality

All data and records generated during the conduct of this study will be kept confidential in accordance with Nemours policies. Data and associated records will be used for the sole purpose of the conduct of this study.

Additional steps to ensure the privacy and confidentiality of participants will also be taken. Unique code numbers will be assigned to each participant and will be used to organize the data files. A file matching the code numbers to

specific participants will be kept in a password-protected computer file that will only be accessible to Dr. Canter and the Research Coordinator. All identifiable information (e.g., consent forms) will be stored in a locked file cabinet in a locked office. Whenever possible, documents containing identifiable information (e.g., letters explaining the study prior to recruitment) will not be kept electronically or in printed form. Confidentiality will be discussed with all participants at the time of consent.

Spanish language interpreters who complete the online evaluation form will not be required to provide any personal information.

7. Facilities and Location of Study

This is an eHealth intervention study, meaning that participants can complete all phases of the intervention at a location of their choosing. Consent for the study will be obtained during a previously scheduled medical visit or online via REDCap. No in-person study visits will be scheduled.

The filming of the MFVDG will take place in a room at the Ronald McDonald House in Wilmington, DE.

The Think Aloud testing of eSCCIP-SP will take place either at Nemours/Al DuPont Hospital for Children or remotely if the participant chooses to participate through a video chat platform. If the participant would like to participate in-person, the Research Coordinator will work to find a room to privately conduct the Think Aloud testing.

8. Publication and Presentation Policy

The results of this study may be presented at professional meetings or published in a professional journal. Any personal identifying information will not be included in these presentations or publications.

The video clips from the MFVDG and skill-building videos will be used during trainings for future interventionists (such as psychologists or social workers) who are learning how to deliver this intervention to other families of children with cancer. These video clips may also be included in professional presentations about this intervention (e.g., professional conference presentations), and will also be viewed by caregivers who complete the eHealth intervention (eSCCIP) and the in-person intervention (SCCIP). They will not be used for advertising or marketing purposes. The use of the video clips for the purposes described above are covered by the study informed consent and the Authorization to Release Patient Photo/Video/Audio or other Protected Health Information (PHI) for Publication, and will also be reviewed in person with participants.

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Appendix

- A. eSCCIP-SP Objectives and Aims
- B. Development of eSCCIP-SP
- C. Aim 1 Recruitment Email
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- F. eSCCIP-SP Recruitment Email (Spanish and English version)
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- I. Script for Caregiver Interviews
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Appendix A: eSCCIP-SP Objectives and Aims

Objective and Specific Aims

The Surviving Cancer Competently Intervention Program (SCCIP; R01CA63930) is an in-person psychosocial intervention for families of children with cancer with a strong evidence base. SCCIP uses principles from cognitive behavioral and family therapy to decrease posttraumatic stress symptoms and improve family functioning. The original SCCIP was a day-long workshop for adolescent cancer survivors and their parents and siblings (Kazak et al., 1999; Kazak et al., 2004). SCCIP has since been developed into an online intervention program. eSCCIP, an innovative eHealth intervention based on an efficacious intervention for caregivers of children with cancer (SCCIP-ND) has been developed as an accessible tool to provide critical psychosocial care to caregivers of children with cancer. eSCCIP is comprised of four online modules. Each module is comprised of a unique mix of original video content and interactive activities, and is complemented by a brief telehealth follow-up with an interventionist. The aim of this study is to develop a Spanish version of the eSCCIP (eSCCIP-SP) and determine the acceptability of the adaptation for key stakeholders.

This study will create a new resource for Spanish-speaking families. It will provide these families with psychosocial care that will help support them through the cancer trajectory. The use of technology is novel and involving families in project development (i.e., prototype testing) is highly consistent with the Nemours True North mission. In addition to making psychosocial care accessible to a broader group of families, online intervention tools may be a cost effective approach to providing this care. This study will be an important first step in providing a critical service to Spanish-speaking families of children with cancer.

Appendix B: Development of eSCCIP-SP

This study includes the development (i.e., eSCCIP-SP) of an efficacious intervention for Spanish-speaking families to decrease psychological distress and risk for PTSD for children with cancer and their families. eSCCIP-SP will follow the same structure as eSCCIP: three technology-assisted follow-up sessions with a trained interventionist after the completion of each online module. Results from this study will be used to develop and conduct a larger scale trial of eSCCIP-SP, with the long-term goals of making eSCCIP-SP widely available to caregivers of children with cancer.

1.1. Development of Online Interactive Tools

Articulate Storyline 2 software will be used to develop the initial prototype of eSCCIP-SP. This involves a number of steps: 1) develop online interactive tools based upon cognitive-behavioral principles (e.g., identifying beliefs that may cause distress) 2) develop video content (e.g., writing scripts and recording videos to explain key therapeutic principles) 3) integrate video and interactive content, ensuring that content is presented in a visually appealing and logical manner, and ensuring seamless integration with our online delivery platform. Dr. Canter will work closely with Center for Pediatric Traumatic Stress staff who have extensive experience using Articulate Storyline 2 to build and deliver eLearning programs (e.g., courses on trauma-informed care for nurses). Expert consultation will also be provided at this phase from Dr. Lee Ritterband, who is a leading expert in eHealth within the field of health psychology. Dr. Ritterband is currently a PI or Co-I on seven federally funded eHealth studies, and has also pioneered several innovative and widely cited theories for developing and utilizing eHealth interventions.

1.2. Specific eSCCIP-SP Module Content

eSCCIP has three sessions, and components of each will initially be reconfigured into an Spanish language, interactive, user- friendly online module with different components , including videos and interactive worksheets. More specifically, each module will include interactive "clickable" web- based content, such as brief slideshows and activities, which will be accessible anywhere that participants have access to an internet-equipped computer. Each module will also include brief "teaching" videos (< 5 minutes in duration; see appendix for an example script), where Dr. Canter or Dr. Kazak will provide an overview of a key skill to supplement the interactive content. The content of these videos will be based on evidence-based content from the in-person SCCIP intervention and grounded in core cognitive-behavioral and family-systems theory. These videos, as well as the multifamily video discussion group, will be viewable at any time, as long as there is access to an internet-equipped computer. Participants will be able to complete the module in one sitting or may complete components at different times. All content will also remain available to be viewed repeatedly by the participant. The only component of the intervention that will need to be scheduled with an interventionist is the brief telehealth follow-up that will serve to review intervention content and answer any questions. By providing a range of options for completion of the session material, eSCCIP-SP will be highly adaptable and flexible, which is critical for this population. Per recommendations by experts in the field (Wu et al., 2014), the development of our Spanish language version of eSCCIP will be an iterative process, and we will build our site module by module in an effort to quickly identify and correct any unanticipated challenges. This

process corresponds directly to several steps in Ritterband and colleagues' (2003) nine-step model for developing interventions, including operationalizing an efficacious intervention by identifying critical ingredients (step 3), transforming treatment components into engaging internet content (step 5), and building the intervention (step 8). An outline of eSCCIP, with proposed components to be translated into eSCCIP-SP, is provided in the sections that follow modules outlined in Section 3.1.

1.3. Development of Multifamily Video Discussion Group (MFVDG) Content

A key component of eSCCIP is the use of multiple family video discussion groups (MFVG), which have been previously filmed and serve as a proxy of participants' interaction with other parents. The videos are designed to capture themes common among caregivers of children with cancer (e.g., anger, guilt, emotional exhaustion), examples of coping (e.g. putting things in perspective, connecting with others, using humor as appropriate), and impact on the family over time (e.g., siblings, grandparents, thinking about the future). They are also meant to stimulate further thought and conversation about the caregivers own experiences with cancer. The video family discussion groups are well-received by caregivers (Kazak et al., 2005). However, the current videos used in eSCCIP are only available in English. In order to ensure that the videos remain relevant and are reflective of our diverse patient population, the development of eSCCIP-SP will include recording new video family discussion groups to use in the intervention. We will work with oncology leadership to identify a diverse group of participants (in terms of child's cancer diagnosis, treatment phase, age, race, ethnicity, socioeconomic status, and family structure) and approach families about participation in this endeavor. A group of five families would be ideal for this group. Interested caregivers will be consented in accordance with IRB policies prior to being filmed and will be compensated for their time. These caregivers will be a part of the "eSCCIP-SP family council". In addition to participating in the filming of the videos, the eSCCIP-SP family council may also review edited videos and other materials in order to provide feedback on this critical component of project development.

By agreeing to participate in the MFVDG component of the study, participants in the multifamily video discussion group are agreeing to the release/broadcast of identifiable information about themselves and their child. The uses of these videos are explicitly detailed in the consent form, and will be reviewed with the participants prior to the initiation of any filming. Any participants who are not comfortable being filmed in this capacity will be able to opt out prior to the beginning of filming. Additionally, participants will be able to opt out at any point during the day of filming by telling a member of the study team that they no longer wish to participate. Participants will also be able to opt out of the video group during the video editing process, up until the videos have been finalized. Any participant who withdraws in this manner will be edited out of all of the final videos by our videography team.

1.4. Development of Skill-Building Videos

All of the eSCCIP-SP modules will include "teaching" videos, which will feature Dr. Kazak and/or Dr. Canter providing an overview of a key therapeutic skill to be used by participants. Interviews with other study personnel and clips from the MFVDG may also

be integrated into these skill-building videos. Scripts for these videos will be written by Drs. Kazak and Canter, and will be recorded by Dan Huber (Video Action Productions).

1.5 Think Aloud Testing of eSCCIP-SP

Five Spanish-speaking caregivers of children with cancer will be asked to review the first version of eSCCIP-SP through a think-aloud testing session. Purposeful sampling will be used to ensure adequate representation of diversity of cancer diagnoses (e.g., leukemia, solid tumors). Eligible caregivers will be approached in person or by phone about participation in the study by Spanish-speaking study personnel.

Think-Aloud testing is a widely used technique for collecting preliminary usability and feasibility data for eHealth interventions. Five Spanish-speaking families will be recruited to participate in Think-Aloud testing. In order to quickly identify any challenges and adapt the prototype as needed, the first three families who participate in Think-Aloud testing will be scheduled appointments to test eSCCIP-SP. Caregivers can choose whether they would like to review eSCCIP-SP in one study session or two shorter study sessions. Any changes that are deemed necessary after the review of each module will be made. This will allow for rapid responsiveness to participant feedback and quick refinement of the intervention.

After consent to participate is obtained, participants will be given a secure log-in and password to access the modules on the eSCCIP-SP website. For caregiver convenience, participants can choose to either participate in-person at Nemours/Al Dupont Hospital for Children or remotely through a Nemours approved video chat platform. All Think-Aloud sessions will be recorded.

Appendix C: Recruitment Email for Focus Group

Dear _____,

We know that having a child with cancer is hard. Many families feel upset and benefit from receiving support for their child and family. Our research group has developed an online intervention for parents and caregivers of children with cancer. It's called eSCCIP, or Electronic Surviving Cancer Competently Intervention Program. eSCCIP offers support to caregivers as you navigate this hard time. It is based off a current in-person intervention that aims to help families cope with pediatric cancer.

Your cancer care team has identified you as someone who might be interested in participating in helping us further develop eSCCIP. We would like to get your feedback regarding your thoughts on the eSCCIP website as well as any potential challenges caregivers might face when completing an online intervention.

We will be holding a focus group with other caregivers of children with cancer to gather feedback. The one-time session will be approximately two hours and will be led by Kimberly Canter, Ph.D., who is the principal investigator for this study. We will provide dinner and childcare, and you will be compensated for your participation. We will follow-up by phone or in-person to discuss this project and your potential involvement in more detail within the next two weeks. This decision is entirely yours, and your response will not affect your child's care in any way.

If you would like to opt out, have any questions, or would like more information about our project, please contact one of the study coordinators, Alejandra Perez Ramirez at alejandra.perezramirez@nemours.org or (302) 298-7571 or Gaby Vega at gabriela.vega@nemours.org; (302) 298-7937.

We hope to speak with you soon.

Sincerely,

Appendix D: Aim 2 Recruitment Letter

Dear

We know that having a child with cancer is hard. Many families feel upset and can benefit from additional support for their child and family. Our research group here at Nemours has developed a new online program for parents and caregivers of children with cancer, called eSCCIP (The Electronically Surviving Cancer Competently Intervention Program). Our team worked very hard to create eSCCIP in order to provide families with extra support during this difficult time.

****Please take a moment to review the flyer included in this envelope to learn more about eSCCIP and how it can help you and your family. ****

We are currently looking for parents and caregivers to participate in a research study testing eSCCIP. If you agree to participate, we will send you a set of online surveys to complete prior to starting the program. We will then send you a unique username and password to log on to the eSCCIP website. You can complete eSCCIP entirely online. It can be done anywhere and completely at your convenience (on your phone, tablet, or computer). Once you complete eSCCIP, you will be asked to complete another set of online surveys. You will be paid \$50 for your participation.

If you want to learn more or are interested in trying eSCCIP, please contact Alejandra Perez Ramirez (study coordinator) by phone at 302-409-0593, or by email at Alejandra.PerezRamirez@nemours.org. If you do not want to be contacted regarding this research opportunity, please let us know by phone or email. If we do not hear from you, we will contact you by phone in about 1 week. We hope you are willing to take part in this important work.

Sincerely,

Kimberly Canter, Ph.D.

Psychologist, Center for Healthcare Delivery Science

Anne Kazak, Ph.D., ABPP

Co-Director, Center for Healthcare Delivery Science

APPENDIX E: FLYER



What is eSCCIP?

eSCCIP (pronounced E-Skip) is an online program for caregivers of children diagnosed with cancer. It helps families better understand their beliefs about cancer and its treatment, learn and practice alternate ways to look at distressing beliefs, and imagine a future where cancer is less prominent.

eSCCIP is comprised of three modules:



Module 1: ABC Model

Helps caregivers understand the relationship between Adversities, Beliefs, and Consequences.



Module 2: Footsteps to Reframing

Helps caregivers recognize thoughts that are unhelpful and use manageable steps to come up with more helpful thoughts.



Module 3: Family Survival Map

Helps caregivers reflect on their experiences so far and imagine where they might be headed next.

Each module contains interactive activities as well as videos of other families who have experienced similar things.

What will I do in eSCCIP?

You will be asked to complete each module, one at a time. After each one, you will have an opportunity to meet with your interventionist through a video call. This could be a social worker, psychologist, or therapist. During the call, you will be able to discuss what you have learned in the module and how you can apply it in your life. Scan the QR Code with your mobile device to learn more about eSCCIP and our team!



For more information, please contact Alejandra Perez Ramirez either by phone at 302-409-0593 or by email at Alejandra.PerezRamirez@nemours.org



eSCCIP is copyrighted by the Nemours Center for Healthcare Delivery Science (CHDS). It may not be used or modified in any form without prior written permission from the Center.

APPENDIX F: Spanish Recruitment Email

Estimado/a [Nombre del participante]:

Nosotros estamos conscientes de que tener un hijo/a con cáncer es difícil. Muchas familias se sienten tristes, pero se pueden beneficiar cuando reciben ayuda y apoyo para su hijo/a y familia. Nuestro equipo de investigadores ha creado un programa de intervención disponible en línea para padres o quienes están al cuidado de niños con cáncer. Se llama eSCCIP, por sus siglas en inglés, o el Programa Electrónico de Intervención para Superar el Cáncer Competentemente. eSCCIP le ofrece ayuda y apoyo para que usted y su familia puedan manejar sus sentimientos de mejor manera durante este tiempo difícil. Por el momento, la intervención solo está disponible en el idioma inglés, pero nos gustaría traducir y adaptar el programa para familias cuya lengua principal es el español.

Usted ha sido nominado por su equipo médico del hospital como alguien que estaría interesado en participar en este estudio. El primer paso de este proyecto será grabar un video de una conversación con varios padres de niños con cáncer. En esta conversación, hablaremos sobre temas relacionados de sus experiencias con su hijo con cáncer. La conversación se llevará de 3-5 horas en un día.

El cuidado de niños estará disponible y le proveeremos la comida. Al terminar la conversación, también recibirá una tarjeta de débito de \$100. En las próximas dos semanas, le estaremos contactando por teléfono o en su próxima cita en el hospital. Le hablaremos en más detalles sobre el proyecto y como se puede involucrar en nuestro proyecto.

Si le gustaría participar o si tiene más preguntas sobre el estudio, por favor contáctense con Alejandra Perez Ramirez al 302-298-7571 o Alejandra.perezramirez@nemours.org o Gaby Vega al 302-298-7937 o Gabiela.vega@nemours.org.

¡Esperamos hablar con usted pronto!

Gracias,

APPENDIX F: Spanish Recruitment Email (translated in English)

Dear _____,

We know that having a child with cancer is hard. Many families feel upset and benefit from receiving support for their child and family. Our research group has developed an online intervention for parents and caregivers of children with cancer. It's called eSCCIP in English, or Electronic Surviving Cancer Competently Intervention Program. eSCCIP offers support to caregivers as you navigate this hard time. It is based off a current in-person intervention that aims to help families cope with pediatric cancer. eSCCIP is currently only available in English, but we would like to adapt and translate it for Spanish-speaking families.

Your cancer care team has identified you as someone who might be interested in participating in this study. The first step of adapting eSCCIP in Spanish is recording a multi-family video discussion with various caregivers who have children with cancer. During this discussion, we will talk about your experience with your child with cancer. It will last approximately 3 to 5 hours in one day.

We will provide dinner and childcare, and you will be compensated for your participation. You will receive a \$100 gift card at the end of the discussion. We will follow-up by phone or in-person to discuss this project and your potential involvement in more detail within the next two weeks. We will talk to you about the project in more detail and how you can get involved.

If you would like to participate or have any questions about our project, please contact one of the study coordinators, Alejandra Perez Ramirez at alejandra.perezramirez@nemours.org or (302) 298-7571 or Gaby Vega at gabriela.vega@nemours.org or (302) 298-7937.

We hope to speak with you soon!

Sincerely,

Appendix G: Gift Card Letter

[INSERT DATE]

Dear [INSERT PARTICIPANT NAME],

Thank you for participating in the study, "Pilot Testing eSCCIP: An eHealth Intervention for Parents of Children with Cancer." This letter includes your gift card compensation for study participation. This gift card will be loaded with \$50 on it once it has been activated.

Your gift card is NOT ACTIVATED/LOADED with MONEY.

To activate your gift card:

- Please contact Gaby Vega at gabriela.vega@nemours.org or (302-298-7937).

OR

- Please contact Alejandra Perez Ramirez at alejandra.perezramirez@nemours.org or (302- 298-7571).

You will be asked to provide the following information:

- Your Full Name
- The gift card number o Shown on the front of the card as "THANKS XXX" □
Participating child's date of birth

If you choose email, you will receive an email reply when the card is activated.

Thank you,

Kimberly Canter, PhD
Study Principal Investigator

Gabriela Vega, M.S
Study Coordinator

Alejandra Perez Ramirez, B.A.
Study Coordinator

Appendix H: Script for Caregiver Focus Group

Script for Caregiver Focus Group

Materials: eSCCIP modules on big screen, printed screenshots of modules, video prepped on laptop and tablets, sample recruitment materials for feedback (flyers)

Equipment: Digital audio recorder

Time: Approximately 90 minutes

Reminders of Key Principles for Facilitating Focus Groups

- *Remember to treat this as a conversation – be aware of power differentials.*
- *Let the participants lead and provide information that they feel is important. As the interviewer, your job is to probe issues to obtain greater depth and facilitate a discussion between and among participants as this has the potential to bring out unique perspectives and fresh ideas.*
- *Things to avoid:*
 - *Leading questions*
 - *Individuals dominating the group*
 - *Moving too quickly from one topic to the next*
 - *Interrupting the interviewee (in most cases, see below)*
 - *Confirmations such as “yes” or “right” (Try, “uh huh”; “ah” or “I see”)*
- *Things to do:*
 - *Join with the participants before the group and at the beginning of the group.*
 - *Be comfortable with silence! Participants may be processing*
 - *Use probes: Who, what (e.g. what do you do?), where, when, how (e.g. how do you feel?), why [limit use – implies that a correct answer exists], describe, tell me about, what was happening at the time*
 - *Ask for more information when something is confusing or seems contradictory*
 - *Reflect back what you hear*
 - *Actively invite input from others if individuals begin to dominate*
 - *As you formulate perspectives on what you are being told, express that and ask if you have it right – be open to being corrected (“I think I am hearing you say ... Is that right?)*
 - *Provide closure at the end of the group; e.g. do a “round robin.”*
- *Rephrase questions using participants words*

- *It's ok to interrupt a participant who goes on a tangent. Just be sure to do it tactfully – e.g. "switching gears", visual cue*

Welcome and Introduction

Thank you for taking the time for this focus group. Before we begin, I want to review what we will talk about today. As we go along, feel free to stop me if you have any questions.

Key Points:

- Providing psychosocial care to help patients and families is an important part of treatment
- We have developed eSCCIP, which is our online program for caregivers of children with cancer. Up to two caregivers from the same family can participate, and caregivers do not have to be parents. Some of you have already participated in eSCCIP, and some of you have not.
- eSCCIP is adapted from an in-person program. We are hoping that the online version will allow us to help even more families.
- We want to focus tonight on understanding how we can make eSCCIP as interesting, important, and engaging to parents as we can. We want to make sure that we are doing everything that we can to keep people interested and engaged in eSCCIP after they agree to participate, and to develop recruitment procedures that make it easy for parents to start eSCCIP and complete all the sessions.
- Your feedback is very important to us and will help us make improvements to the program before testing it with a larger group of families. Your participation today will help us provide better services to families who have a child with cancer.
- All information will be confidential. The tapes are confidential and will not be shared with people outside of our research team. They will be stored on password protected computers. Our conversation tonight won't be linked in any way to identifying information about you or your child.
- Do you have any questions?
- Do you agree to participate? (*Consent procedures as determined with IRB review will be followed*).

Introductions:

To get started, let's briefly learn a little bit about each other. We're going to keep everyone to a maximum of 90 seconds! Please share your name, child with cancer's name, child's diagnosis, and your opinion about the pros and cons of participating in online programs.

About eSCCIP:

We'd like to provide a brief overview of eSCCIP. The purpose of eSCCIP is to provide parents and caregivers with additional tools to help cope with the challenges associated with cancer diagnosis and treatment. By doing so, we hope to help improve overall family functioning, and decrease things like anxiety, distress, and posttraumatic stress. eSCCIP has four separate self-directed parts, which we call modules. The first is an introduction to the program. Then, there are three core sessions with content, which are followed by a telehealth, or video, follow-up with a therapist. We have some screenshots of eSCCIP, and we will return to these later.

About Recruiting Caregivers into the Study:

Research Coordinator to talk briefly about current recruitment procedures.

- What is eSCCIP?
 - If you were approached about eSCCIP, what type of information you would like to have before deciding whether or not to participate in the program?
 - What type of information would you like to have before deciding whether or not to participate in a study evaluating the program?
 - How should this information be provided to parents and families?
 - What questions or concerns might you have about participating in eSCCIP?
 - What about a study evaluating the program?
 - Please share any thoughts about what we can do to alleviate any concerns about participation.
- When to approach parents?
 - We are interested in learning about the best time and place to approach caregivers about participating in eSCCIP. Please discuss your thoughts about

this. For example, should we reach out during hospitalizations or outpatient appointments?

- Who is the best person to initially introduce eSCCIP to caregivers of children with cancer? What is the best way for this person to contact caregivers about the program?
 - Prompt for more detailed information – print media, email, video overview
- We are interested to hear your thoughts about the timing of eSCCIP. For example, are there times during treatment when this program would be particularly helpful or, on the contrary, times when it would not be helpful?
- Related to this question – when would it be most helpful to first learn about eSCCIP?
- Who should be approached?
 - We are interested in supporting all parents and families of children with cancer, and we want to make sure that we provide support to individuals who need it the most. Many times, individuals who are most “at risk” – for example, people who report very high levels of distress - are less likely to participate in programs focused on social or emotional health. Should we concentrate on individuals who may be most at risk? How can we engage these caregivers?
 - Are there any individuals who should not be approached about participating in eSCCIP?
 - Please share your thoughts about multiple caregivers from the same family participating in eSCCIP. What advantages do you see about including multiple caregivers? How about any disadvantages?
 - What thoughts do you have about how to best engage multiple caregivers from the same family to participate in eSCCIP?
- What are barriers to participation?

- What are logistical barriers to participating in a program like eSCCIP? How about a study evaluating eSCCIP? We want to make sure that things like reliable access to the internet or busy schedules do not prevent people from participating in eSCCIP. Please discuss any barriers that might prevent someone from joining our study.
- What are emotional or social barriers to participation? Please share any feedback about the potential impact of this sort of barrier.
- What about barriers that might come up over the course of participating in eSCCIP? How about over the course of participating in a study evaluating eSCCIP? Participation takes about one month from start to finish.
- What would facilitate participation?
 - [For each barrier identified above] What supports could we provide to help eliminate any barriers that might emerge?
 - What supports could we provide to help any unexpected barriers that might come up after caregivers agree to participate?

About onboarding and scheduling:

Research coordinator to talk briefly about current onboarding/ set-up procedures.

- What ideas do you have about teaching caregivers how to use the different components of eSCCIP? How should this be done?
 - Probes: in person, by phone, by video, over email?
- How could we help caregivers understand the different parts of eSCCIP? For example, what would help you remember your log-in and how to get to the website?
- What kind of reminders and help with scheduling would be beneficial for you?
- What would you like to have access to between eSCCIP sessions – for example, would features like being able to bookmark pages or see your text responses be helpful to you?

About keeping participants interested :

Research coordinator to talk briefly about current procedures (text reminders, emails)

- What would be helpful for keeping caregivers interested and engaged throughout the whole program?
 - Please discuss any supports that our research team can provide during the program. For example, what can we do to make it easier for participants to complete the online modules and telehealth follow-up?
- What are some ideas that you have for customizing the program to meet individual needs?
 - Please discuss your thoughts about the degree of flexibility that we should offer caregivers who are participating in eSCCIP. For example, should telehealth sessions be optional? Should we offer in-person follow-up?
 - In families with two interested caregivers, how should eSCCIP be tailored to meet the needs of both caregivers? How about the completion of the website and telehealth follow-up?
- What about follow-up?
 - How can we ensure that we are identifying high levels of distress during the program and providing appropriate follow-up supports and resources?
 - What kind of follow-up, if any, would be useful after completing eSCCIP?
 - *If appropriate, prompt for more specific information about type of follow-up (e.g., telehealth check-ins, formal outpatient therapy), utility of community referrals, ongoing access to eSCCIP website.*

About Website:

- We are interested in learning more about how your family uses technology. Do you have access to a tablet/computer/smartphone at home, work or someplace else that is convenient? Please tell us about the devices that you use on a regular basis.

- *Prompt: Do these devices have internet access?*
- What type of device and where would be most convenient for completing eSCCIP?
 - *Prompt about devices that are already accessible, and also ask about technology that the family may not have (such as a tablet).*
- Where would you use this device to complete eSCCIP?
- (Pull up features of eSCCIP using screenshots and power point display)
 - What features would you expect when you use the website?
 - For example, are there certain functions that we could develop that would make the user experience better for participants? It might be helpful to think about other websites that you frequently use, and what you like about those websites.
- Before we wrap up our focus group, please provide us with any other feedback about eSCCIP that you feel would be important or helpful for us to know.

Appendix I: Script for Caregiver Interviews

Script for Caregiver Interviews

Materials: eSCCIP modules on big screen, printed screenshots of modules, video prepped on laptop and tablets, sample recruitment materials for feedback (flyers)

Equipment: Digital audio recorder

Time: Approximately 90 minutes

Reminders of Key Principles for Conducting Qualitative Interviews

- *Remember to treat this as a conversation – be aware of power differentials.*
- *Let the participant lead and provide information that they feel is important. As the interviewer, your job is to probe issues to obtain greater depth and facilitate a discussion between and among participants as this has the potential to bring out unique perspectives and fresh ideas.*
- *Things to avoid:*
 - *Leading questions*
 - *Individuals dominating the group*
 - *Moving too quickly from one topic to the next*
 - *Interrupting the interviewee (in most cases, see below)*
 - *Confirmations such as “yes” or “right” (Try, “uh huh”; “ah” or “I see”)*
- *Things to do:*
 - *Join with the participant before the group and at the beginning of the group.*
 - *Be comfortable with silence! Participant may be processing*
 - *Use probes: Who, what (e.g. what do you do?), where, when, how (e.g. how do you feel?), why [limit use – implies that a correct answer exists], describe, tell me about, what was happening at the time*
 - *Ask for more information when something is confusing or seems contradictory*
 - *Reflect back what you hear*
 - *As you formulate perspectives on what you are being told, express that and ask if you have it right – be open to being corrected (“I think I am hearing you say ... Is that right?)*
- *Rephrase questions using participants words*
- *It’s ok to interrupt a participant who goes on a tangent. Just be sure to do it tactfully – e.g. “switching gears”, visual cue*

Welcome and Introduction

Thank you for taking the time for this interview. Before we begin, I want to review what we will talk about today. As we go along, feel free to stop me if you have any questions.

Key Points:

- Providing psychosocial care to help patients and families is an important part of treatment
- We have developed eSCCIP, which is our online program for caregivers of children with cancer. Up to two caregivers from the same family can participate, and caregivers do not have to be parents. Some of you have already participated in eSCCIP, and some of you have not.
- eSCCIP is adapted from an in-person program. We are hoping that the online version will allow us to help even more families.
- We want to focus tonight on understanding how we can make eSCCIP as interesting, important, and engaging to parents as we can. We want to make sure that we are doing everything that we can to keep people interested and engaged in eSCCIP after they agree to participate, and to develop recruitment procedures that make it easy for parents to start eSCCIP and complete all the sessions.
- Your feedback is very important to us and will help us make improvements to the program before testing it with a larger group of families. Your participation today will help us provide better services to families who have a child with cancer.
- All information will be confidential. The tapes are confidential and will not be shared with people outside of our research team. They will be stored on password protected computers. Our conversation tonight won't be linked in any way to identifying information about you or your child.
- Do you have any questions?
- Do you agree to participate? (*Consent procedures as determined with IRB review will be followed*).

Introductions:

To get started, let's briefly learn a little bit about each other. Please share your name, child with cancer's name, child's diagnosis, and your opinion about the pros and cons of participating in online programs.

About eSCCIP:

We'd like to provide a brief overview of eSCCIP. The purpose of eSCCIP is to provide parents and caregivers with additional tools to help cope with the challenges associated with cancer diagnosis and treatment. By doing so, we hope to help improve overall family functioning, and decrease things like anxiety, distress, and posttraumatic stress. eSCCIP has four separate self-directed parts, which we call modules. The first is an introduction to the program. Then, there are three core sessions with content, which are followed by a telehealth, or video, follow-up with a therapist. We have some screenshots of eSCCIP, and we will return to these later.

About Recruiting Caregivers into the Study:

Research Coordinator to talk briefly about current recruitment procedures.

- What is eSCCIP?
 - If you were approached about eSCCIP, what type of information you would like to have before deciding whether or not to participate in the program?
 - What type of information would you like to have before deciding whether or not to participate in a study evaluating the program?
 - How should this information be provided to parents and families?
 - What questions or concerns might you have about participating in eSCCIP?
 - What about a study evaluating the program?
 - Please share any thoughts about what we can do to alleviate any concerns about participation.

- When to approach parents?
 - We are interested in learning about the best time and place to approach caregivers about participating in eSCCIP. Please discuss your thoughts about this. For example, should we reach out during hospitalizations or outpatient appointments?
 - Who is the best person to initially introduce eSCCIP to caregivers of children with cancer? What is the best way for this person to contact caregivers about the program?

- Prompt for more detailed information – print media, email, video overview
 - We are interested to hear your thoughts about the timing of eSCCIP. For example, are there times during treatment when this program would be particularly helpful or, on the contrary, times when it would not be helpful?
 - Related to this question – when would it be most helpful to first learn about eSCCIP?
- Who should be approached?
 - We are interested in supporting all parents and families of children with cancer, and we want to make sure that we provide support to individuals who need it the most. Many times, individuals who are most “at risk” – for example, people who report very high levels of distress - are less likely to participate in programs focused on social or emotional health. Should we concentrate on individuals who may be most at risk? How can we engage these caregivers?
 - Are there any individuals who should not be approached about participating in eSCCIP?
 - Please share your thoughts about multiple caregivers from the same family participating in eSCCIP. What advantages do you see about including multiple caregivers? How about any disadvantages?
 - What thoughts do you have about how to best engage multiple caregivers from the same family to participate in eSCCIP?
- What are barriers to participation?
 - What are logistical barriers to participating in a program like eSCCIP? How about a study evaluating eSCCIP? We want to make sure that things like reliable access to the internet or busy schedules do not prevent people from participating in eSCCIP. Please discuss any barriers that might prevent someone from joining our study.

- What are emotional or social barriers to participation? Please share any feedback about the potential impact of this sort of barrier.
- What about barriers that might come up over the course of participating in eSCCIP? How about over the course of participating in a study evaluating eSCCIP? Participation takes about one month from start to finish.
- What would facilitate participation?
 - [For each barrier identified above] What supports could we provide to help eliminate any barriers that might emerge?
 - What supports could we provide to help any unexpected barriers that might come up after caregivers agree to participate?

About onboarding and scheduling:

Research coordinator to talk briefly about current onboarding/ set-up procedures.

- What ideas do you have about teaching caregivers how to use the different components of eSCCIP? How should this be done?
 - Probes: in person, by phone, by video, over email?
- How could we help caregivers understand the different parts of eSCCIP? For example, what would help you remember your log-in and how to get to the website?
- What kind of reminders and help with scheduling would be beneficial for you?
- What would you like to have access to between eSCCIP sessions – for example, would features like being able to bookmark pages or see your text responses be helpful to you?

About keeping participants interested :

Research coordinator to talk briefly about current procedures (text reminders, emails)

- What would be helpful for keeping caregivers interested and engaged throughout the whole program?

- Please discuss any supports that our research team can provide during the program. For example, what can we do to make it easier for participants to complete the online modules and telehealth follow-up?
- What are some ideas that you have for customizing the program to meet individual needs?
 - Please discuss your thoughts about the degree of flexibility that we should offer caregivers who are participating in eSCCIP. For example, should telehealth sessions be optional? Should we offer in-person follow-up?
 - In families with two interested caregivers, how should eSCCIP be tailored to meet the needs of both caregivers? How about the completion of the website and telehealth follow-up?
- What about follow-up?
 - How can we ensure that we are identifying high levels of distress during the program and providing appropriate follow-up supports and resources?
 - What kind of follow-up, if any, would be useful after completing eSCCIP?
 - *If appropriate, prompt for more specific information about type of follow-up (e.g., telehealth check-ins, formal outpatient therapy), utility of community referrals, ongoing access to eSCCIP website.*

About Website:

- We are interested in learning more about how your family uses technology. Do you have access to a tablet/computer/smartphone at home, work or someplace else that is convenient? Please tell us about the devices that you use on a regular basis.
 - *Prompt: Do these devices have internet access?*
- What type of device and where would be most convenient for completing eSCCIP?
 - *Prompt about devices that are already accessible, and also ask about technology that the family may not have (such as a tablet).*

- Where would you use this device to complete eSCCIP?
- (Pull up features of eSCCIP using screenshots and power point display)
 - What features would you expect when you use the website?
 - For example, are there certain functions that we could develop that would make the user experience better for participants? It might be helpful to think about other websites that you frequently use, and what you like about those websites.
- Before we wrap up, please provide us with any other feedback about eSCCIP that you feel would be important or helpful for us to know.

Appendix J: Telehealth Script (Module 1)

Module 1 Telehealth Review

Identifying Beliefs about Cancer:

Using **The ABC Model** to Understand the Relationship Between Adversities, Beliefs and Consequences

Learning Goals of Module 1:

Identify beliefs about cancer, its treatment, and the impact on the family.

1. Identify beliefs about illness and treatment.
 2. Examine how beliefs influence emotions, behaviors, and relationships.
 3. Recognize how each family members beliefs influence the whole family.
 4. See that beliefs are normal and feel less isolated and alone.
-

1. Begin each session checking-in with the family

2. Review of Module 1 Content

Ok. I wanted to begin by talking about your reactions to Module 1 and the content.

[Briefly Review Videos] *First, let's talk about the videos of the family discussion group. Did you connect with anything that was said or did anything jump out?*

[Review the ABC Model] *Let's talk about the tool that you were introduced to and that's the ABC model. So you learned about how beliefs [The "B"] about an adversity [The "A"] has consequences [The "C"] in terms of how we feel, act, and relate to others. So you can think of:*

A/Adversity = Things that are tough, sad or scary

B/Beliefs = Thoughts or feelings related to the Adversity

C/Consequences = Outcomes, or the way things turn out due to the impact of our feelings and actions on others.

***It's important to note that:**

Beliefs are not good or bad and it's individual. Each family members has their own thoughts and beliefs about a challenge or adversity.

Free Response Exercise Review - The ABC Model: Your Experience

Let's talk about your own responses you shared in the free response segment of Module 1

[Interventionist has reviewed the free responses prior to the telehealth session. It is important that interventionists are incorporating the family's own work that they have done into each telehealth follow-up.]

- **Review responses that inquire if there are other examples that might be helpful to discuss**

Are there questions you have about the ABC tool?

- Prompt for what other family members might be thinking

- Prompt for outcomes/consequences for other caregivers

3. Summary

Do you see the value of just being aware of this process? It's really a new way of coping with emotional and social challenges. This tool helps us to be aware of how a particular belief about a challenge:

- *Makes me feel*
- *What I do when I feel that way*
- *And, the impact that might have on my relationships with other family members, medical team. My child, etc.*

4. Wrap-Up and Set-Up for Module 2

*With the next module you will get a better understanding of The "B", beliefs about adversities and how our next tool called **The Footsteps Strategy** can help you to reframe beliefs in a way that enhances family functioning and better coping.*

Module 1 Free Response Exercise: The ABC Model- Your experience

Adversity: Use the box to type in your own adversity.

Belief: Use the box to enter a belief for each caregiver related to the adversity you entered in the previous box.

Consequence: Use the box to enter a consequence of the adversity and belief you entered earlier.

Appendix K: Telehealth Script (Module 2)

Module 2 Telehealth Review Footsteps to Reframing Changing Beliefs: *The Footsteps Strategy*

Learning Goals of Module 2 –

Identify beliefs about cancer, its treatment, and the impact on the family

1. See that having distressing beliefs at the diagnosis and treatment of your child's cancer is understandable and normal.
 2. Recognize the link between distressing beliefs and consequences.
 3. Watch families in the videos use *The Footsteps Strategy* to reframe their beliefs to enhance family functioning.
 4. Practice using *The Footsteps Strategy* to reframe a distressing belief of your own.
-

1. Begin each session checking-in with the family

2. Any Module 1/ABC follow-up?

3. Review of Module 2 Content

Ok. I wanted to begin by talking about your reactions to Module 2 and the content.

[Review *The Footsteps Strategy*] *Let's talk about the tool that you were introduced to: **The Footsteps Model or Strategy**. It seems simple but it does take some effort. It is a different way of looking at adversity. It's a process of changing your beliefs or, reframing. And, as the module stressed, **it is not that your beliefs are good or bad**, it's just that there are times when a different belief or perspective is more helpful. We really do all get stuck in our beliefs at times and this is a tool that helps us get "unstuck."*

So let's review the 4 specific footsteps

Let go of uncontrollable: *Recognize what is beyond your control. In the video, one of the mothers was talking about how she is "a controlling mom" and how she had to let go of that. Another parent in the clip talked about coming to terms with "the fact that I can't fix this."*

Controllable: *Focus on things you can control like asking for help. In the video one of the parents was talking about the family looking at treatment days as "being in the cancer world" and, focusing on routine and living their lives as normally and "care free" as possible when they were not in the "cancer world"*

Acknowledge and apply your strengths and your family's strengths: *What strengths have helped you in the past? In the video, one of the dads was talking about how sense of humor has always helped them to cope with challenges.*

Using positives to your advantage: *Looking at adversity through a different lens. For example, in the video, a father was talking about watching his daughter take her pills with an*

attitude of, “let’s just get through this and move on ... we will be one step closer to being cancer-free.” He said, “a light bulb went off and I decided we needed to be more positive, like her.”

Free Response Exercise Review – Applying the 4 Footsteps: Your Experience

Now, let’s talk about your own responses you shared in the free response segment of Module 2 **[Interventionist has reviewed the free responses prior to the telehealth session. It is important that the interventionists are incorporating the family’s own work that they have done into each telehealth follow-up.]**

- **Review responses than inquire if there are other examples that might be helpful to discuss.**

Finally, can we think about one of the adversities we talked about last time and apply the footsteps?

4. Summary

So by applying **The Footsteps Strategy** to upsetting and difficult situations it helps us to reframe or look at the adversity in a different way that can have more positive consequences for you, your child, and family.

5. Wrap-Up and Set-Up for Module 3: *The Family Survival Roadmap*

Any questions about the two tools: **the ABC Tool** and **The Footsteps Strategy**?
The last module you will be introduced to a tool we call **The Family Survival Roadmap**. This helps you to navigate the cancer experience by reflecting on where you have been, where you are now and where you might be in the future. It is a tool that can help to put cancer in its place.

Module 2 Free Response Exercise

1. **Accept the uncontrollable:** Spend a few moments thinking about an uncontrollable aspect of your experience.
2. **Focus on the controllable:** Think about controllable aspects of your experience.
3. **Acknowledge strengths:** Think about some of the strengths that you have an individual and as a family.
4. **Use the positive:** Reflect and think about how the previous footsteps can help you see the challenge in a new and different light.

Appendix L: Telehealth Script (Module 3)

Module 3 Telehealth Review *The Family Survival Road Map*

Helps caregivers to share beliefs about the family's future and continued growth

Learning Goals of Module 3:

Imagining the future can help to put cancer in its place.

1. Consider the role that cancer will have on your family in the future.
 2. Understand the role of present beliefs on your beliefs about the future.
 3. Recognize the potential benefits of using *The Footsteps Strategy* to reframe thoughts and beliefs as you think about the future.
 4. Imagine a future where cancer may be less prominent.
-

1. **Begin each session checking-in with the family**
2. **Any additional thoughts about the ABC Model or Footsteps to Reframing**
3. **Review of Module 3 Content**

Ok. I wanted to begin by talking about your reactions to Module 3 and the content.

[Briefly Review Videos] *First, let's talk about the videos of the family discussion group. Did you connect with anything that was said or did anything jump out?*

Metaphors: *This segment also talked about using metaphors to help explain your experience to others. Metaphors like:*

- Cancer - the unwelcome visitor*
- Roller Coaster*
- Tornado*

Did any of these resonate with you? Do you have others you and your family use?

[Family Survival Roadmap] *Let's talk about the tool that you were introduced to – **The Family Survival Roadmap**. What did you think about the map?*

Free Response Exercise Review - – **The Family Survival Roadmap: Your Experience**

Let's talk about your own responses you shared in the free response segment of Module 3

[Interventionist has reviewed the free responses prior to the telehealth session. It is important that interventionists are incorporating the family's own work that they have done into each telehealth follow-up.]

- **Review responses and keep focused on the interpersonal :**

Where were you?

Tell me about why you picked _____.

Where were others then?

Tell me about where you think others were then and why do you think they were there.

Where are you now?

Tell me about why you picked _____.

Where are others now?

Tell me about where you think others are now and why you think they are there.

- What is it like to be at different places?
- What do you need to come closer together?
- What role is cancer playing in your life right now?

Where are you going?

Thinking about the future – let’s imagine a day in the future when cancer isn’t center stage. An example from the video was when one of the dads talked about still worrying about relapse but less focused on it.

Tell me about why you picked _____.

Where are others going?

Tell me about where you think others are going and why you think they may be going there?

- What looks different, how has it changed you as a family?
- Thinking about the footsteps – what you’ve let go of, what you can control, new strengths you have ... anything positive you can see as a result of this future?
- Moving forward – are there things that you have learned, thought about, or practiced that will be helpful to you and your family moving forward? Things you will discuss with other family members?

4. Summary

Do you see the value of using this tool? As the module suggests, just as you have a treatment roadmap, **The Family Survival Roadmap** helps you to navigate the cancer experience.

5. Wrap-Up and Logistics

- Do you need any additional support or follow-up?
- You can expect to receive post-intervention measures through REDCap.
- A \$50 gift card will be mailed to you after the measures have been completed

Thank you!

Module 3 Free Response Exercise: **The Family Survival Roadmap – Your Experience**

Where were you?

Tell me about why you picked _____.

Where were others then?

Tell me about where you think others were then and why do you think they were there.

Where are you now?

Tell me about why you picked _____.

Where are others now?

Tell me about where you think others are now and why you think they are there.

Where are you going?

Tell me about why you picked _____.

Where are others going?

Tell me about where you think others are going and why you think they may be going there?

Appendix M: Telehealth Fidelity Checklist

eSCCIP Module 1 Fidelity Checklist

| General Skills | Exceeds Expectations | Meeting Expectations | Below Expectations |
|--|----------------------|----------------------|--------------------|
| 1. Actively listens while participant is talking | | | |
| 2. Communicates in a respectful, positive, non-judgmental manner | | | |
| 3. Appropriately reinforces ideas and opinions | | | |
| 4. Adheres to telehealth session time limit | | | |

| Module 1 Content | Present | Absent |
|---|---------|--------|
| 1. Reviews video of family discussion | | |
| 2. Elicits reactions to family video | | |
| 3. Review ABC model | | |
| 4. Reviews A component | | |
| 5. Reviews B component | | |
| 6. Reviews C component | | |
| 7. Discusses beliefs as neither good nor bad | | |
| 8. Reviews own family example for ABC model | | |
| 9. Elicits questions about ABC model | | |
| 10. Summarizes impact of beliefs about a challenge | | |
| 11. Introduce Module 2 | | |
| 12. Discusses how beliefs impact other family members | | |

eSCCIP Module 2 Fidelity Checklist

| General Skills | Exceeds Expectations | Meeting Expectations | Below Expectations |
|--|----------------------|----------------------|--------------------|
| 1. Actively listens while participant is talking | | | |
| 2. Communicates in a respectful, positive, non-judgmental manner | | | |
| 3. Appropriately reinforces ideas and opinions | | | |
| 4. Adheres to telehealth session time limit | | | |

| Module 1 Content | Present | Absent |
|---|---------|--------|
| 1. Introduces The Footsteps Strategy | | |
| 2. Reviews 1 st footstep (uncontrollable) | | |
| 3. Reviews 2 nd footstep (controllable) | | |
| 4. Reviews 3 rd footstep (strengths) | | |
| 5. Reviews 4 th footstep (using positives) | | |
| 6. Apply 1 st footstep to own experience | | |
| 7. Apply 2 nd footstep to own experience | | |

| | | |
|--|--|--|
| 8. Apply 3 rd footstep to own experience | | |
| 9. Apply 4 th footstep to own experience | | |
| 10. Summarizes The Footsteps Strategy | | |
| 11. Introduce Module 3 | | |
| 12. Elicit questions about ABC Tool/Footsteps Strategy | | |

eSCCIP Module 3 Fidelity Checklist

| General Skills | Exceeds Expectations | Meeting Expectations | Below Expectations |
|--|----------------------|----------------------|--------------------|
| 1. Actively listens while participant is talking | | | |
| 2. Communicates in a respectful, positive, non-judgmental manner | | | |
| 3. Appropriately reinforces ideas and opinions | | | |
| 4. Adheres to telehealth session time limit | | | |

| Module 1 Content | Present | Absent |
|--|---------|--------|
| 1. Reviews video of family discussion | | |
| 2. Elicits reactions to family video | | |
| 3. Review metaphors in video | | |
| 4. Elicits reactions to metaphors | | |
| 5. Introduce Family Survival Roadmap | | |
| 6. Apply Family Survival Roadmap to own experience | | |
| 7. Emphasizes relationships on Roadmap | | |
| 8. Summarizes Family Survival Roadmap | | |
| 9. Assesses need for additional support | | |
| 10. Remind to complete post-intervention measures | | |

Appendix N: Interpreter Questionnaire

Please tell us about your experience working on the eSCCIP translation project. In answering these questions, please think about the time you spent with the research team working on translating and adapting eSCCIP (our online program for caregivers of children with cancer) into the Spanish eSCCIP version (eSCCIP-SP).

1. Please describe your overall experience translating and adapting content from eSCCIP into eSCCIP-SP for Spanish-speaking families.
2. Please describe any concerns that you have about the adaptation or interpretation process. Is there anything you would change about the process?
3. Please describe your overall thoughts about eSCCIP-SP. Is there anything you would remove or add to eSCCIP-SP?
4. Please share your thoughts about delivering eSCCIP-SP to Spanish-speaking families.
5. Please share your thoughts about working with the research team.
6. Please share any general thoughts about support services and resources available to Spanish-speaking parents at Nemours.
7. On a scale of 1 to 5, please rate your overall experience working on the eSCCIP translation project.

| | | | | |
|-----------|------|---------|------|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Very Poor | Poor | Neutral | Good | Very Good |

Appendix O: Caregiver Demographic Form

eSCCIP Demographic Form

Your Gender (✓ one): Male Female Other

Your Age Range (✓ one)

20-29 30-39 40-49 50-59 60-69 70+

Race (✓ all that apply)

White Black or African American Asian
 American Indian or Native Alaskan Native Hawaiian or Other Pacific Islander
 Other _____

Ethnicity (✓ one) Hispanic or Latino Non-Hispanic or Latino

Marital Status

Single Married/Partnered Divorced Widowed Other _____

Education (✓ one)

Started school but didn't finish Finished High school/got GED
 Started college or trade school Finished college or trade school
 Started master's or doctoral program Finished master's or doctoral program

Annual Household Income (✓ one)

Less than 24,599 25,000 to 49,999 50,000 to 74,999
 75,000 to 99,999 100,000 to 124,999 125,000 to 149,000
 150,000 or more

Child's Diagnosis: _____ Diagnosis Date: _____

Age_____ Male Female Other

Do you have other children? Yes No

Age_____ Male Female Other

Age_____ Male Female Other

Age_____ Male Female Other