# An Innovative Tailored Intervention for Improving Children's Postoperative Recovery (WebTIPS)

Protocol

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# A Tailored Internet-Based Preparation Program for Pediatric Perioperative Anxiety and Pain (WebTIPS)

**CHOC Children's Hospital** (Reviewing IRB, Participant Recruitment)

**UC Irvine** (CMU relying IRB, No Patient Recruitment)

**Seattle Children's Hospital** (Sub-Site, Independent IRB)

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**Sponsor:** National Institute of Health

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**Background & Significance:**

Over five million children undergo surgery in the United States each year. Up to 65% of these children develop significant pain after surgery and high anxiety prior to surgery. Not only are anxiety and pain emotionally traumatic, but recent data indicates that high perioperative stress can also lead to adverse postoperative psychological and physiological outcomes. Indeed, recent research has found that untreated postoperative pain may lead to delayed hospital discharge, delayed wound healing, and the development of chronic pain syndromes. High preoperative anxiety in children is associated with increased postoperative pain, delayed hospital discharge as well as maladaptive postoperative behavioral changes and emergence delirium. Modalities such as preoperative sedatives, postoperative analgesics and behavioral preoperative preparation programs are available at the current time to help children to cope with perioperative pain and anxiety. Despite the availability of such interventions, both postoperative pain and preoperative anxiety continue to be undertreated in many children undergoing surgery.

Reasons for this under treatment include cost-containment efforts, lack of information and training for parents in pain management, and parental patterns of insufficient analgesic administration. Although many hospitals used to offer comprehensive behavioral preparation programs several days prior to surgery, currently less than 20% of children receive such preparation; instead, 80% of the hospitals currently offer a shortened program delivered on the day of surgery just before surgery. This practice change is likely due to the overwhelming shift toward outpatient surgery and cost-containment efforts that discourage time-intensive behavioral interventions in hospitals. Data obtained by our study group, have shown that anesthesiologists, surgeons, and nurses each spend less than 6 minutes on the day of surgery with outpatient children. Clearly, the rationale that day of surgery preparation can replace the traditional preparation programs that are conducted several days prior to the procedure is simply not valid. The recent dramatic growth in the use of the World Wide Web provides an opportunity to create an innovative Internet based intervention that will be accessed multiple times during the perioperative period and that will integrate evidence-based treatments for improving postoperative pain management and reducing preoperative anxiety. Further, the Internet allows such an intervention to be tailored to empirically chosen characteristics of the child, parent and the surgical procedure. Over the past fifteen years, our laboratory has been involved in multiple interdisciplinary studies aimed at identifying risk factors, developing interventions and assessing outcomes of perioperative pain and anxiety.

We have currently developed an intervention program tailored to individual outcome variables, called Web-based Tailored Intervention for Preparation for Surgery (WebTIPS). The outputs are tailored based on parent and child characteristics previously found to be related to perioperative anxiety and pain and are described below. A clinician and researcher module has also been developed to provide information about the parent and child.

**Purpose:** The purpose of this study is to test the efficacy of a Web-based Tailored Intervention Preparation for Surgery (WebTIPS) versus WebINFO, the attention control group program, targeted at children ages 1-12 undergoing outpatient elective surgery, and their parents.

A generic outline of the WebTIPS output is provided below:

***Parent Output***

**OUTPUT 1: Home Before Surgery (preoperative)**

The first module of this intervention provides parents with information that will be important to consider before the day of surgery. This module is unique, because in addition to typically provided information about NPO guidelines and directions, this module attends to parent anxiety by addressing worries and providing training in specific anxiety management techniques. We have conducted extensive literature searches and consulted with experts to identify the most common parental worries about surgery. We have used input from surgeons, anesthesiologists, and child life specialists to provide psychoeducation to address these beliefs. Consultation with psychologists with expertise in anxiety management and review of current literature was used to develop a relaxation training protocol including guided imagery of a distracting scene. Providing this training to parents at home before surgery allows for repeated practice in a comfortable atmosphere.

**OUTPUT 2: Surgery**

The next module focuses on the day of surgery and the pre-operative holding area. We have used transcripts collected from certified child-life specialists to ensure that information about checking in and preoperative visits by healthcare staff is consistent with what is typically offered by this discipline. We have expanded on typical preparation programs by providing state-of-the-art information on Midazolam and parental presence at anesthesia induction (PPIA). This information can be used by parents to make informed decisions about their preference for treatment.

This module also includes anesthesia induction and surgery. This is based on our previous work evaluating pharmacological and behavioral interventions to manage parents' and children's anxiety at anesthesia induction. The subsection on parental presence at induction of anesthesia (PPIA) is evidence-based and is built upon the ADVANCE program (Kain et al., 2007). We have also included the provision of music to parents in the waiting area based on our previous work indicating that this technique decreased perioperative anxiety.

**OUTPUT 3: Recovery Room - Post Anesthesia Care Unit (PACU)**

In terms of pain management, we have used an interdisciplinary approach to address the multiple facets of children's pain. In addition to pharmacological management, this module provides parents with specific instructions on the implementation of behavioral strategies to minimize pain. Behavioral strategies receiving coverage are the most up-to-date, empirically supported interventions available for children ages 2-5 years. This novel approach provides parents and children with opportunities to practice with these instruments; a necessary step because young children often have difficulties understanding pain scales and require practice to use these scales effectively.

**OUTPUT 4: Home after Surgery (postoperatively)**

The following module benefits from the same thorough development process as the PACU pain module and extends the utility of this preparation program to management of children's pain at

home. Given that parents hold the primary responsibility for children's care at home, it is imperative that they are provided with information about, and support for, the administration of pain management strategies in this setting. The innovative approach of this module offers unparalleled opportunities to address barriers to optimal pain management at home. For example, recent evidence of parental attitudes as a barrier is accounted for by providing information tailored to parents' unique misconceptions about pain management strategies. Further, the accessibility offered by this web-based module addresses availability limitations of traditional preparation programs; parents can continue to access up-to-date information after they have left the surgical center and when questions arise at home.

***Child Output***

As with parent modules, the child component of the WebTIPS program is based on the most up-to-date research literature. It was developed in consultation with clinical child psychologists, developmentalists, and child life specialists who are experts in tailoring complex information to be developmentally appropriate. The child output includes an overview of the surgical process including an interactive operating 360° virtual room tour as usually accomplished on an in-person visit. The output also includes training children in distraction and deep breathing and includes a component of imaginal exposure which is similar to that offered in the shaping intervention recently validated by our research team.

***Clinician Output***

Clinicians will be provided with information to engage the child on the day of surgery, such as the child's favorite games, toys, movies, and hobbies, which will have been input by parents into the intake portion of WebTIPS. Clinicians will use this information to quickly build rapport with the child on the day of surgery and may also be able to use this information to aid in distraction during anesthesia induction. The clinician module of WebTIPS will also provide a summary of parents' and children's intake variables within the web-based program. That is, clinicians will be informed of parents' preferred coping styles (monitor or blunter) anxiety level (high or low) and children's temperament (fearful or non-fearful). Accompanying these summaries will be tips for clinicians to tailor their day of surgery behavior to parents' and children's characteristics. These tips include communication that directs the child's attention away from the procedure and towards a fun topic, as well as providing health information to the parent in the amount of detail adequate for their coping style. In addition, clinicians will have information regarding parental preferences on the day of surgery, such as whether the parent would prefer their child receive a sedative premedication and whether the parent would like to be present for their child's anesthesia induction, if allowed by hospital policy. It is important to note that WebTIPS will comply with the most recent HIPPA regulations.

**PHASE 1**

**Study Aims & Hypotheses**

**Primary Aim:** To examine the feasibility and utility of the web based intervention and its effect on preoperative anxiety of the child.

- Hypothesis 1: We expect WebTIPS to significantly reduce anxiety of the child and parent before surgery.

**Secondary Aims:**
1) To examine how WebTIPS affects children's recovery in the post-anesthesia care unit through pain intensity and emergence delirium.

- Hypothesis 1: We expect WebTIPS to significantly reduce both intensity and emergence delirium (ED).

2) To examine how WebTIPS affects children's home clinical recovery by assessing pain, maladaptive behavioral changes, and quality of life.
- Hypothesis 2: We expect WebTIPS to significantly reduce pain intensity and maladaptive behaviors and enhance return to normal activity.

3) To examine the feasibility and utility of the web based intervention and its effect on preoperative anxiety of the parent.
- Hypothesis 3: We expect WebTIPS to significantly reduce preoperative anxiety in parents.

4) To assess parent satisfaction outcomes.
- Hypothesis 4: We expect patient satisfaction scores to be improved.

5) To assess how WebTIPS affects resource utilization through admission rates, visits to the ER, and surgery cancellations.
- Hypothesis 5: We expect reduction in cancellations, unexpected admissions, and ED visits, as well as reduced anesthesia induction and PACU time (which translates to lower resource utilization).

**Methods:**

**Study Design**

This is a two-arm single blind, randomized controlled trial to test the efficacy of WebTIPS vs WebINFO in 620 children undergoing surgery at two children's hospitals serving communities in California and Washington State. We plan to recruit 310 parent-child dyads per study site, in which they will be part of the intervention phase that lasts up to 20 days.

Children will be randomly assigned to one of two groups: the WebTIPS Group or the WebINFO group. Participants will be informed that the purpose of the study is to evaluate web-based methods of preparing parents and children for surgery as well as decreasing anxiety and postoperative pain, through a comparison of WebTIPS and WebINFO.

With a credible attention control group such as WebINFO, the study can test if WebTIPS is effective beyond the participants' expectations from being placed in an intervention group. WebINFO will mimic WebTIPS in its medium (website and mobile application) and its appearance (layout), however it will not provide skills training, child interaction, or patient-tailored information.

- WebTIPS Group: This intervention group will receive the WebTIPS intervention described above in the WebTIPS general outline. WebTIPS includes information provision, modeling and teaching of coping skills such as guided imagery, relaxation techniques, and breathing exercises. It addresses the entire perioperative experience from the minute the decision was made until 14 days after surgery.

- WebINFO Group: WebINFO, the developed attention control group, provides vast information on the perioperative process but is generic in nature and does not use any tools such as coping enhancement, relaxation techniques, modeling or behavioral exposure.

**Parent-Child Dyad Eligibility**

*Inclusion Criteria*

Participants will include children ages 1-12 years who were born at least 36 weeks gestational age, and who are scheduled to undergo outpatient surgery at CHOC Children's Procedure Center. Attached to this submission are a list of surgeries that are eligible to participate in this study. Parent or guardian of child must be an English speaker.

Additionally, parents or guardians of children whose health status is American Society of Anesthesiologists (ASA) physical status I-III will be recruited for this study. ASA status I refer to "patients who are normal and healthy with no known systemic disease". ASA status II refers to "patients who have mild or well-controlled systemic diseases," such as non-insulin dependent diabetes, upper respiratory conditions, well-controlled asthma or allergies. ASA status III refers to "patients who have moderate or severe systemic disease, which does limit their activities (e.g., stable angina or diabetes with systemic sequelae)."

*Exclusionary criteria*

Children born before 36 weeks gestational age or have a history of chronic illness are excluded from this study. In addition, children with surgeries not listed below will be excluded since the WebTIPS program provides tailored output for these surgery types.

| | |
|---|---|
| **Otolaryngology(ENT)** | Tonsillectomy<br>Adenoidectomy<br>Tonsillectomy and Adenoidectomy<br>Branchial Cleft Syst Removal<br>Ear Drum Repair<br>PE Tubes/Ear Tubes<br>Tympanoplasty<br>Otoplasty<br>Otoscopy<br>BSAER<br>Endoscopy/Laryngoscopy<br>Frenulum Repair |
| **Pediatric General & Thoracic Surgery** | Appendectomy - open incision<br>Appendectomy- laparoscopic incision<br>Ankyloglossia Repair (Tongue Release)<br>Central Line Placement |
| **Ophthalmology** | Cataract Removal<br>Chalazion Excision/Removal<br>Frontalis Suspension<br>Strabismus Repair<br>Tear Duct Dilation or Probing |

| | |
|---|---|
| | Eye Tubes |
| **Orthopedics** | Bone Marrow Aspiration<br>Bone Setting/Spica Cast<br>Lumbar Puncture<br>Open Reduction of a Fracture<br>Osteotomy<br>Tendon Lengthening/Bone Spur<br>Syndactyly Correction |
| **Plastic Surgery** | Cauterizing of Nostrils<br>Cleft Lip/Palate Repair<br>Nervus/Mole Removal<br>Septoplasty/ Sinusotomy<br>Scar Revision/Skin Graft |
| **Urology** | Circumcision<br>Hernia Repair<br>Hydrocelectomy<br>Hypospadius Repair<br>Meatoplasty<br>Orchiopexy |

Non-English speaking participant dyads will not be enrolled at this time. Due to the cultural components that the PI will test in a future study, WebTIPS - Healthcare disparities, the current mobile health application has been developed in English only. Because the Latino population has unique barriers (e.g. provider communication, empathy, cultural sensitivity) in the management of pain and recovery after surgery, the PI will be submitting a grant to culturally tailor and translate the WebTIPS application and will then recruit Spanish-speaking participants.A parent or guardian of children with health status defined by ASA status IV-V will be excluded from this study. ASA status IV refers to “patients with an incapacitating systemic disease that is a constant threat to life”. ASA status V “patients are considered moribund”.

Lastly, parents or guardians of children who are not in the normal range of development will not be eligible for this study. This will be assessed by report from the parents. The rationale for excluding patients with developmental delay is that due to their cognitive impairments, such children react to the stressors of surgery differently than do children without such developmental delay. It is unclear how such children would use the preparation programs and interventions included in this study, and it is likely that their responses on baseline and outcome measures will differ from children of normal developmental parameters.

**Procedures**

***Preoperative Period (Timepoint 1)***

*Enrollment and Randomization: 15-30 days prior to surgery*: Potential parent-child dyads will be identified through review of the operating room (OR) schedules at CHOC Children’s. In order to screen for eligibility, it is necessary to view protected health information (PHI) before mailing/emailing study introductory letters, calling patients regarding study interest, and approaching potential patients at scheduled appointments due to a wide variety of surgeries that

occur in the Tidwell Procedure Center. Therefore, a waiver of HIPAA authorization has been requested to ensure only eligible subjects are approached. Potential dyads will be assessed for eligibility by review of the electronic medical record using the exclusionary criteria as seen in the uploaded document titled "Recruitment Eligibility Data Sheet." Families of patients who are determined to be eligible will be mailed or emailed a letter of introduction that describes the purpose of the study, study requirements, and contact information for study personnel 1 month prior to surgery day. A week after mailing the letter, the research associate will call the parents of potential subjects to answer any questions they may have and invite participation. If parent-child dyad is eligible and interested, a researcher will schedule a phone call with parent-child dyads to explain all study information, and consent through the electronic platform (see attached recruitment script).

Oftentimes, surgeries are not scheduled weeks in advance so a research associate will also review the schedules for add-ons and when time permits, they will call families up to 6 days prior to surgery to explain the study and invite their participation by phone. Meetings at the parent-child dyad's home will only be scheduled for the daytime with two researchers, and only when the parent is present. If dyad schedules the appointment at the UCI Center on Stress and Health, transportation will be provided to the participant at no cost. For those participants where time does not allow mailing an introduction letter, the research associate will email the introduction letter to participants interested in the study. Because of the preoperative component of WebTIPS and WebINFO, it will not be possible to recruit families on the day of surgery.

*Intervention Period: 5-30 days prior to surgery:* Potential parent-child dyads will be provided contact information for study personnel, an electronic HIPAA authorization form, and an electronic informed consent form. Both the HIPAA authorization and informed consent forms require their electronic signature. The research associate will thoroughly describe the study and both the patient and parent will be asked if they are interested in participating. Parent-child dyads will be asked if they have any questions concerning the study and all questions will be answered thoroughly and candidly. Parents will be asked to read the electronic informed consent and the child will also be asked to read the age-appropriate assent form (if 7 years old or older). If the participant dyad wishes to participate, the study will be thoroughly described and the risks, benefits and alternatives to participation will all be explained. Participants will also be informed that they are free to discontinue the study at any time, for any reason, and without any adverse effects. Participants will be asked if they have any questions concerning the study and all questions will be answered thoroughly and candidly. Subjects will be identified by a randomly assigned identifying number for coding and analyzing data. All data forms, files, and computer databases will be stored in a secure location at the PI's research offices. Confidentiality of each participant's data will be monitored closely and we will adhere to the newest privacy regulations imposed by HIPAA. Randomization will be centrally controlled and a secure, web-based randomization service (www.randomize.net) will be used for allocating participants to WebTIPS or WebINFO.

We will assure that all parents can access a mobile device (desktop, laptop, tablet, smartphone) during the intervention period. If the family does not have access, we will provide the families a device and a data plan for the duration of the study. A signed property form (see attached in submission) will be needed to lend the device, and an RA will assure that the family knows how to use the device. Participants will be informed that questionnaire links will be sent via email and text. Variables collected include baseline demographics (e.g. age, sex), as well as parental coping (MBSS), parent anxiety (STAI-T), child fear (CBQ), and parental pain management attitudes (MAQ). The RA will also make sure that families are clear about how to access WebTIPS / WebINFO. Subjects will be supplied with a unique password that will enable them

access for 5 days before surgery and 14 days after surgery. We will ask parents to access the WebTIPS or WebINFO at least 24 hours prior to surgery but they can log on as many times as they wish for 20 days after their account is created. Once the family has received the log in information, the research associate will call the family and walk them through the log in process over the phone. A study email has been created to allow the parent to e-mail the researchers if any questions arise.

For participant dyads in the WebTIPS groups, parents will have the ability to interact with research staff via SMS two-way communication. In the preoperative phase, SMS messages regarding adherence and reminders will be sent to parents. If the participant was randomized to WebTIPS, the patient's anesthesiologist will receive an email three days before the patient's surgery with login information to WebTIPS to access the clinician output.

***Day of Surgery (Time point 2)***

*Preoperative holding area:* RA will collect parent self-reported anxiety (STAI-S). RAs will videotape the preoperative holding area during T2. Due to the extended period of time each patient may spend in holding and to avoid inefficient use of time, RAs will not conduct in vivo coding. The last 20 minutes of each video will be coded.

*Separation to the OR:* RA will assess child anxiety (m-YPAS), and collect parent self-reported anxiety (STAI-S).

*Operating room:* Child anxiety and interactions (m-YPAS) will be observed in vivo at two time points: 1) upon entering the OR/Procedure Room and 2) upon introduction of the anesthesia mask to the child.

*Post-Anesthesia Care Unit (PACU):* Emergence status (PAED), incidence of adverse effects, vomiting, fluid intake and time to discharge will be noted. Nurses blinded to treatment condition will assess children's pain (FLACC) (ages 1-12) every 15 minutes. The use of analgesia in the OR and in the PACU will also be noted (Analgesic Abstraction). In addition, any complaint related to pain will immediately trigger an evaluation with FLACC regardless of the pain assessment schedule.

***Postoperative Period (Time point 3)***

*Home: Postoperative Days 1-14:* Following discharge home, parents will log into REDCap from home to complete measures of satisfaction, pain ratings (PPPM, FPS-R), medication administration, and recovery (PedsQL). For participants in the WebTIPS group, the FPS-R will be administered as an SMS. Parents in both groups will record type and amount of medications administered, if any (Pain Medication Form) every night. Use of overnight medication will be recorded on the following days' entry. Parents will be asked to complete the FPS-R questionnaires first thing in the morning and at bedtime. Parents will be asked to complete the PPPM nightly. The outpatient surgery satisfaction questionnaire will be completed the morning of day 1. Parents will also complete a measure of maladaptive behavioral changes (PHBQ-AS) on days 5, 7 and 14, and the PedsQL on the night of day 5.

During the postoperative period, participants will be provided an opportunity to pose questions or concerns to the department staff (i.e. nurse practitioner, nurse, physician) via SMS in the postoperative period and receive individualized responses. The research assistants will filter messages in order to forward messages to the patient's appropriate department staff.

Additionally, if a WebTIPS parent responds a major pain response for their child, research assistants will forward the pain response to the patient's appropriate department. A research assistant will call the participant dyad periodically to assure adherence to study protocol. Parents will be instructed to follow their doctor's office instructions regarding emergencies.

*Home: 14-30 days after Surgery:* Data regarding patient satisfaction (NRC), 30-day admission rates, 30-day visits to PCP, 30-days visits to ED and PACU times will be obtained from the quality departments at both hospitals. These data are routinely collected and available for use in the proposed study (See Chief Medical Officer support letter).

**Compensation**

Parent-child dyads in the WebTIPS and WebINFO group will be paid $ 25 in the form of a target gift card after each completed time point during the study. There are three time points in this study: time point 1 consists of baseline questionnaires and access to the program done at home, time point 2 consists of day of surgery questionnaires, and time point 3 consists of postoperative questionnaires. The total compensation for participation in the entire study is $75 in the form of gift cards. If patient-child dyads decide to withdraw from the study or are withdrawn by the research team, participants will receive compensation for the time points that they have completed. The study information sheet will include information about the financial compensation. Target gift cards may be given in person, mailed, or emailed.

For WebTIPS and WebINFO, adherence in time point 1 will be assessed by baseline survey completion and the number of pages accessed of the WebTIPS intervention or WebINFO viewed by the parent, as seen in the administrative site of the program. In addition, for both groups the time point 3 gift cards will only be sent upon receipt of completion of at least 80% of questionnaires through REDCap or by mail.

Participating health care providers will not be compensated for assisting in study procedures

**REDCap E-consent:** REDCap accounts are provided by UCI Health Sciences, and require special permission to distribute and access surveys. Traditional hard copy Informed consent/assent and HIPAA authorization will be phased out and will now be collected via REDCap. There will be designated fields for parent name and signature, along with participant name and signature.

**E-consent process:** Electronic-Consent (e-Consent) is a platform for consenting research participants either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. Potential parent-child dyads will be provided contact information for study personnel, an electronic HIPAA authorization form, and an electronic informed consent form as it is approved by CHOC IRB. Both the HIPAA authorization and informed consent forms require their electronic signature. Participants will be asked if they have any questions concerning the study, and all questions will be answered thoroughly and candidly.

Potential participants will be asked to sign the electronic informed consent and will be provided with study information which includes, 1) research/purpose/procedures, 2) risks, 3) benefits 4) alternatives, 5) confidentiality, 6) compensation for injury, 7) whom (and how) to contact study personnel, 8) the voluntary nature of human research and the ability to withdraw participation, 9) investigator termination of subject participation, 10) additional costs, 11) consequences of

withdrawal, 12) reporting of significant new findings and 13) the approximate number of subjects to be enrolled, and 14) information on use and disclosure of PHI.

Eligible participants will also be informed that they are free to discontinue the study at any time, for any reason, and without any adverse effects. All research data will be identified only by a randomly assigned ID number, and subject identifier keys/participant tracking will be housed in a separate password protected excel file on a CHOC share drive until participant dyad has signed the electronic informed consent, granting the sharing of PHI with UCI. Once authorization is granted, PHI will be stored on Microsoft SharePoint. E-consent forms will be printed out weekly through REDCap and delivered to CHOC Health Information Management for compliance.

**How the e-Consent Framework works:** The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process. 1) Before a participant completes the survey, an extra certification page is added to end of the Informed Consent form and HIPAA authorization that displays an in-line PDF copy of their responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. (screenshots of certification page have been added to the IRB package) 2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting. The participant will receive and email auto generated from REDCap with a message that reads “Thank you for participating in the WebTIPS Study. Attached you will find a copy of the consent forms you signed. If you have any questions, please contact the WebTIPS study coordinator. Contact information is found below.” (a copy of the auto generated message has been uploaded for IRB review).

**What is e-Consent version and type?**
e-Consent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF. Versioning of a form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version or state of the form. So if the form is modified AFTER data collection begins, then it is recommended that a new version be applied. For example, the first version might simply be '1', and after collecting the consent of a few participants, a co-investigator or aim of the study is modified or added, which represents a new version of the form, thus will increment the version to '2' (and so forth).

**Disclaimer**: Participants will also be informed that WebTIPS and WebINFO are not designed to provide medical advice nor are they substitutes for a nurse or a doctor. If they are experiencing symptoms they would like to discuss, they need to call their doctor. If they are experiencing a medical emergency, they should dial 911.

**Risks and Benefits to Subjects:** Before any research procedures, the research associate will ensure that all subjects fully understand the requirements of the study, and that all their study concerns, if any, are addressed. Prospective participants will be provided with all pertinent information such as purpose, procedures, risks, benefits, alternative to participation, and ample opportunities to ask questions will be allowed. All subjects will be identified only by randomly assigned ID number that will be used on all study documents and data extracts. Subject privacy will be protected by our research staff to the greatest extent possible. All paper-based research documents are stored in locked file cabinets in our locked research office at 505 S. Main Street,

Suite 940, Orange, CA 92868. Only research team members have access to the files. Only authorized personnel have access to the research database, and study investigators will receive data extracts for analysis that contain no subject identifiers. Potential subjects will be reassured that their study participation is voluntary and their refusal will not affect their current or future medical and health care. Subjects may decide they do not want to participate or complete the study at any time and data destroyed at their request.

**Server Information:** PHI obtained prior to parent-child dyad granting e-consent and signing the electronic HIPAA authorization will be stored on a CHOC server (S:\CAPH) in a folder specific to our center (CAPH). These documents will be password protected and accessible only to members of the UCI CSH listed on the personnel chart and RI worksheet. Paper-based recruitment will be kept in a locked filing cabinet in our center located at 505 S. Main St. Suite 940 Orange, CA 92868. After e-consent is obtained, PHI may be stored on Microsoft SharePoint accessible only through UCI Health Sciences intranet using UCI Health Science login credentials. Documents are managed and accessible only to UCI CSH personnel. IP address for the server is not shared with any parties outside of UCI Health Sciences for security purposes.

**Program Security:** Security for both programs (WebTIPS and WebINFO) will be provided via UCI and will include a Secure Socket Layer (SSL) certificate allowing encryption between client and server transactions. Participants will be assigned login names that will not be associated with their real names. All data will be stored and accessed in accordance with the Health Insurance Portability and Accountability Act (HIPPA). Multiple, redundant layers of firewall system will also protect secure data.

**REDCap Surveys:** Research Electronic Data Capture (REDCap) is a secure web application for building and managing databases and surveys widely used in university research. REDCap is hosted by UCI Health Information Technology. Electronic data will be downloaded periodically as a .csv (Comma Separated Values) file or spss (statistical package for the social sciences) file and stored on a secure UCI network in the research office at 505 S. Main Street, Suite 940, Orange, CA 92868. Access to the file will be limited to authorized study staff. Attached to this package is a data dictionary created for REDCap data analysis.

**Analysis Methods**
Statistical analysis will be conducted using Windows SPSS version 23.0 (IBM Inc., Chicago, IL) and SAS version 2.4 (SAS Institute Inc., Cary NC) software owned by the UCI Center on Stress and Health.

We are using well-tested scales to measure outcomes. We will use descriptive statistics, particularly measures of central tendency with dispersion estimates to evaluate all study measures, (e.g. mYPAS.) at each observation point, as well as averaged over all post-operative observation points.

Using mixed effects linear modeling, but without time trends, we will evaluate intervention effects on children's anxiety, and parental coping style (MBSS), as well as type of surgery and child's age and sex. Using separate mixed effect linear models, we will assess intervention effects on postoperative pain (FLACC, FPS-R,), emergence delirium (PAED), adverse effects (measured as a composite of postoperative vomiting etc.), and analgesic requirement. Models will be adjusted for surgery group, sex, and age. Using mixed effect linear models with time trends as noted above, we will assess intervention effects on children's pain (FPS-R), parent-reported pain (PPPM); maladaptive behaviors (PHBQ) and return to normal activities (PedsQL-

acute). Using separate mixed effects linear models, we will examine intervention effect on parental satisfaction (NRC) adjusted for parents' socioeconomic status. Lastly, we will estimate the effect of WebTIPS on resource utilization as summarized by 30-day health care spending, as measured by charges adjusted for each hospital's Medicaid cost-to-charge ratio.

Missing data: Mixed effect linear models are relatively robust to missing data and irregularly spaced observations. Nevertheless, we will evaluate potential for bias in estimation of treatment effects by comparing drop-out rates, rates of 'low use' of interventions and patterns of missing data by treatment group for primary and secondary outcomes, as well as other independent variables and covariates using t-tests for independent samples. We will use intention-to-treat analysis on the primary outcome for the full analytic sample to evaluate bias from missing data. We will consider the use of multiple imputation to estimate scores on study variables as appropriate, and investigate effect of imputation method on treatment effects.

**Measures:**

**Demographics** *(parent self-report)* Baseline demographics will be collected including gender, race, ethnicity, parents' education, occupation, age and income, etc. Regarding ethnicity and culture, the demographics form inquires about detailed information, including cities and countries of parents' previous residence, languages spoken in the home, and parents' and children's primary and secondary languages. In addition, we collect detailed socioeconomic status (SES) information including parent education, occupation, income, and area of residence (i.e., zip code), which will allow us to geocode for detailed SES information regarding the city/county in which participants reside.

**Coversheet** *(Medical record abstraction)* Additional information will be collected from patient medical records including date of surgery, age, weight, procedure, surgery type, surgeon name, anesthesiologist, premedication, premedication amount and notes.

**Child Behavior Questionnaire-Short Form (CBQ)** (Rothbart, Ahadi, Hershey, & Fisher, 2001) *(Parent-report on child):* The CBQ is a highly differentiated assessment of temperament in early to middle childhood. Temperament dimensions for which CBQ scales have been developed have been adapted from dimensions studied in both adults and infants. Three factors have been reliably recovered from this instrument, labeled Negative Affectivity, Surgency, Extraversion, and Effortful Control. There are 15 sub-scales measuring aspects of temperament such as shyness, activity, reactivity, attentional focusing, etc. The CBQ is currently widely used in developmental research and is very well validated (Rothbart et al., 2001).

**Miller Behavioral Style Scale (MBSS*)*** *(parent self-report).* The MBSS assesses parental coping style through four scenarios of stressful situations. This standardized tool was developed for patients undergoing medical procedures and identifies information seekers (monitors) and information avoiders, and distracters (blunters)/nondistractors. In their study of a tailored intervention for mammogram, Williams-Piehota et al. used the two scenario version of the MBSS to categorize participants into high and low monitoring groups (Williams-Piehota, Pizarro, Schneider, Mowad, & Salovey, 2005). These authors calculated a "monitoring score" by subtracting the total number of blunting items from the total number of monitoring responses. Thus, higher scores indicated a higher degree of monitoring coping. This scoring method resulted in excellent test-retest reliability. Consistent with the methodology of Williams-Piehota et al., participants with scores above the median of 4 will be categorized as "high monitors" whereas participants with scores below the median will be categorized as "low monitors".

**Yale Preoperative Anxiety Scale (m-YPAS)** (Kain et al., 1997, 1995)**.** This structured observational measure of preoperative anxiety in children was developed and validated previously by our study group. The YPAS consists of 27 items in five domains of behavior indicating anxiety in young children (Activity, Emotional expressivity, State of arousal, Vocalization and Use of parents). Using Kappa statistics, all YPAS domains have been demonstrated to have good to excellent inter- and intraobserver reliability, and when validated against other global behavioral measures of anxiety, the YPAS had good validity (Kain et al., 1995). The 'adjusted YPAS total score' ranges from 0 to 100 with higher scores indicating greater anxiety. The YPAS was developed originally to measure the anxiety of children while undergoing induction of anesthesia. Recently, we validated the YPAS against a self-report measure, the State Trait Anxiety Inventory for Children (STAIC) (Kain et al., 1997). The m-YPAS will be used to code video recordings of child anxiety during the preoperative holding period, and in-vivo coding for separation, induction 1, and induction 2. *Data Obtained: Standard scores for the anxiety level of children during the perioperative period.*

**State-Trait Anxiety Inventory (STAI)** *(parent self-report, observer report on parent)* (Spielberger, 1983; Spielberger CD, CD, Lushene, Montuori, & Platzek, 1973). This is a widely used self-report anxiety assessment instrument for adults (Spielberger, 1989). To date, over 1,000 studies using the STAI have been published in peer reviewed literature. Standard scores for children and adults are available. The questionnaire contains two separate, 20-item, 4-point self-report rating scales for measuring trait and state anxiety. Total scores for situational and trait anxiety range from 20 to 80 each; higher scores denote higher levels of anxiety. Test-retest correlations for the STAI trait are high and range from 0.73 to 0.86. Validity of the adult instrument was examined in two studies in which the STAI was given under high- and low-stress conditions to large samples of students (Spielberger, 1983). For our purposes, only the one page Trait section of the questionnaire will be administered and utilized.

**State-Trait Anxiety Inventory-Short Form (STAI-SF)** (Spielberger, 1983) The STAI is a commonly used assessment of state and trait anxiety in adults. To shorten this instrument, we made use of our extensive database of 2500 subjects that have participated in our studies. Items with the highest correlations with total scores and face validity (as assessed by our task force) were selected for the shortened versions (11 items on the Trait form). We also realized, however, that changing the medium of the instrument from paper to electronic may have some impact on the concurrent validity. As such, we enrolled 48 parents of children undergoing surgery and asked them to complete both original instruments (paper format) as well as an electronic version of the shortened instruments on a laptop computer**.** Following several revisions we have achieved correlation coefficients of 0.87 to .91. The short version of the STAI trait form will be used in the intake component of the intervention (Kain Z, MacLaren J, Wang S, Caldwell-Andrews A, Yaffa Zisk R, 2006).

**Medication Attitude Questionnaire-Short Form (MAQ-SF)** *(parent self-report)* (Forward, Brown, & McGrath, 1996). This questionnaire was developed to examine attitudes about using pain medication for treating children's pain. Based on our previous studies (Perret, Rony, Fortier, Kain, & Chorney, 2010; Rachel Yaffa Zisk, Grey, Medoff-Cooper, MacLaren, & Kain, 2008), we chose to include the 5 pain management misconceptions most frequently endorsed by parents. These include the following: side effects are something to worry about when giving children pain medication; when giving children pain medication, one should be concerned about addiction or later abuse; pain medication works best when taken rarely and for the worst pain; children feel less pain than adults; and children in pain will express themselves by crying or whining. Each maladaptive attitude endorsed will be matched to a corresponding attitude

modification intervention. Parents endorsing any belief with a score of greater than 2 will receive education about that particular belief.

**Pediatric Anesthesia Emergence Delirium Scale (PAED)** *(parent report)* (Sikich & Lerman, 2004) The PAED rating scale consists of five psychometric items ("child makes eye contact with the caregiver", "child's actions are purposeful", child is aware of the surroundings", child is restless", "child is inconsolable") for the measurement of ED in children. A decreased ability of the child to make eye contact with the caregiver and a declined awareness of his surroundings reflect disturbances in consciousness with a reduced ability to focus, sustain, or shift attention. Less purposeful actions suggest cognitive changes that include perception and memory impairment as well as disorganized thinking patterns. The two other items reflect a disturbance in psychomotor behavior and emotion, although they may also suggest pain or apprehension. The PAED has been shown to be reliable and valid in measuring ED in children (J., J., K.D., K., & Mayer J Rohm KD, Scheuermann K, Suttner SW, 2006; Sikich & Lerman, 2004).

**FLACC Scale (FLACC)** (*Chart review*). This observational pain scale assesses six indicators of pain: Face, Legs, Arms, Cry, and Consolability. Each indicator is rated on a three point scale (0 to 2), yielding a score between 0 and 10 (with higher scores indicative of greater pain). The FLACC was originally designed for children from 4 to 18 years, but has since been used in children as young as 0. The FLACC accurately differentiated between painful and nonpainful phases of procedures, and has shown good to excellent reliability. *Data Obtained: Nurse's FLACC assessments in the PACU following surgery.*

**Analgesic Abstraction** *(Chart review).* Frequency and dose of analgesic administered intraoperatively and in the PACU will be ascertained via chart review. *Data Obtained: Frequency and dose of analgesic.*

**Faces Pain Scale – Revised (FPS-R)** (*Child report*). This children's self-report pain scale consists of a series of six faces ranging from a neutral expression ("no pain") to an expression representing the "most pain possible" (Hicks, Von Baeyer, Spafford, Van Korlaar, & Goodenough, 2001). Scores on the measure range from 0 to 5 and the well-validated scale has been recommended for use with children 4 to 18 years old (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006). The FPS-R has demonstrated good convergent validity with visual analog scale and observational scale ratings of pain (Hicks et al., 2001), and the original FPS has shown good to excellent reliability (Glasman & Albarracín, 2006; R Y Zisk, 2004). *Data Obtained: Self-report pain scores following surgery*

**Parent's Postoperative Pain Measure (PPPM)** *(parent report).* This 15-item measure was developed to help parents assess their child's postoperative pain more reliably (Chambers, Reid, McGrath, & Finley, 1996). Each item refers to an easily identifiable and specific behavior. Items were drawn from parental reports of the cues that parents use to assess pain in their children; the measure aggregates such cues to provide systematic and reliable pain assessment. The measure shows good internal consistency and validity. Items are summed to yield a total score out of 15. A cutoff score of 6 identifies children who have clinically significant pain with excellent sensitivity and specificity. The measure is an appropriate clinical tool for parents because it is brief and requires minimal training.

**Post Hospitalization Behavior Questionnaire for Ambulatory Surgery (PHBQ-AS)** *(parent report).* This self-report questionnaire for parents is designed to evaluate maladaptive

behavioral responses and "developmental regression" in children following hospitalization or surgery (Richard H Thompson; David TA Vernon, 1993; Vernon, Schulman, & Foley, 1966). The PHBQ-AS consists of 11 items frequently cited in the literature as common behavioral responses of children following surgery or hospitalization. We will use the short version that was developed in our lab (Jenkins et al., 2015). Six categories of anxiety are incorporated in this instrument, including General Anxiety, Separation Anxiety, Sleep Anxiety, Eating Disturbances, Aggression Against Authority, and Apathy/Withdrawal. For each item, parents rated the extent to which each behavior changed in frequency as compared to before surgery. This instrument shows acceptable test-retest reliability, good agreement with psychiatric interviews with parents, and predicts changes as a function of preoperative interventions (Vernon et al., 1966).

**Pediatric Quality of Life Acute Version (PedsQL)** (*parent report child ages 2-4, 5-7)* (Varni, Seid, & Kurtin, 2001) The PedsQL measures health related quality of life (HRQOL) in children 2-18 years of age. This 23-item scale is applicable to healthy children as well as children with acute or chronic illnesses. The inventory is divided into 4 categories: physical, emotional, social and school, on a 5-point likert scale ranging from 0=never to 4=almost always (i.e. “I have trouble sleeping”). Higher scores on the scale suggest a better HRQOL. Internal consistency reliability for the total scale score is .88 for the child self-report and .90 to .93 for the parent report. The PedsQL was developed in the U.S., and the reliability and validity is well-established (Varni et al., 2003, 2001).

**Pain Medication Form** *(parent self-report).* The pain medication form will allow evaluate patient medication administration at the end of each day for the entire postoperative period.

**NRC Health Outpatient Surgery Satisfaction** (*parent report) (*Co, Sternberg, & Homer, 2011). This self-report questionnaire for parents is designed to evaluate patient satisfaction with hospital care of children who have undergone outpatient surgery and have been provided with the WebTIPS program.

**Self-reported Health Literacy Questions (parent self-report)**
Three self-reported questions: 1 "How confident are you filling out medical forms?"; 2 "How often do you have problems learning about your medical condition because of difficulty understanding written information?"; and 3 "How often do you have someone help you read hospital materials?" Answers are based on a 5-point Likert scale. (Sarkar et al., 2010)

**Process Measures:**

**Teaching Time**: Data will be collected about the time use of each activity and screen on WebTIPS. Also, teaching time is built into the program; the WebTIPS program will pause at points in which various strategies (e.g., deep breathing) are taught to provide time for parents and children to practice. Data regarding the time the program was paused for will be collected. We will also provide the parents with a diary in which they will report on amount of time spent practicing skills or discussing the intervention with their child outside of computer time. Data will also be collected about the time use and number of visits of each screen on the attention control site (WebINFO).

**Adherence** (1): Observational data will be collected regarding parent and child use of specific core WebTIPS techniques and strategies (e.g. distraction). This data will be collected in the preoperative holding area through a video recording (20 minute segment of entire holding

period), walk to the operating rooms (entire period, 2 minutes in-vivo), induction of anesthesia (entire period, 2-5 minutes in-vivo), and post anesthesia care unit (20 mins. in-vivo observation).

**Adherence** (2): During the induction of anesthesia process we will also collect data about the strategies used by the anesthesiologist who had access to WebTIPS the night before surgery.

**Adherence** (3): At the end of every module in WebTIPS a short quiz will be given to the parents by the program. WebTIPS will not allow parents to progress to the next phase (e.g. from preoperative activities to day of surgery activities) unless they demonstrate their knowledge. This will further ensure the delivery of the intervention and avoid simply clicking on the screen and moving to the next screen.

**Table 1. WebTIPS Measures.** The following table depicts who will fill out each measure, and the time point each measure will be distributed.

| **Time point 1 - Home Before Surgery** | | | |
|---|---|---|---|
| **Outcome** | **Instrument** | **Parent** | **Observer** |
| Age, ethnicity, gender,etc. | Demographics | X | |
| Parent coping style | MBSS (shortened) | X | |
| Child Fear | CBQ (shortened) | X | |
| Parent Anxiety | STAI-SF | X | |
| Parental Attitudes Toward Pain and Analgesics | MAQ | X | |
| Child Quality of Life | PedsQL | X | |
| Health Literacy | Health Literacy Questions | X | |
| **Time point 2 - Holding and Separation** | | | |
| **Outcome** | **Instrument** | **Parent** | **Observer** |
| Parent anxiety | STAI-S | X | |
| Child Anxiety | m-YPAS | | X |
| WebTIPS Parent Techniques | Parent Behavior Form-Adherence | | X |
| **Time point 2 - Operating Room** | | | |
| **Outcome** | **Instrument** | **Parent** | **Observer** |
| Techniques (e.g. Distraction, Reassurance) | Anesthesiologist Behavior Form – Adherence | | X |
| Child Anxiety | m-YPAS | | X |
| **Time point 2 - PACU** | | | |
| **Outcome** | **Instrument** | **Parent** | **Observer** |
| Child emergence delirium | PAED | | X |
| Analgesics Administered, Child Pain | Analgesic Abstraction (Includes FLACC) | | X (From Chart) |

| | | | |
|---|---|---|---|
| WebTIPS Parent Techniques | Parent Behavior Form-Adherence | | X |
| **Time point 3 - Home** | | | |
| **Outcome** | **Instrument** | **Parent** | **Observer** |
| Child Pain | PPPM | X | |
| Child Maladaptive Behavioral Changes | PHBQ-AS | X | |
| Child Quality of Life | PedsQL | X | |
| Child Pain | FPS-R | X | |
| Medication Administered | Pain Medication Form | X | |
| Patient Satisfaction | NRC Health Outpatient Surgery Satisfaction | X | |

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# An Innovative Tailored Intervention for Improving Children's Postoperative Recovery (WebTIPS)

Data Analysis Plan

NCT03730259

***Data Analysis Plan*:**
Statistical analysis will be conducted using Windows SPSS version 23.0 (IBM Inc., Chicago, IL) and SAS version 2.4 (SAS Institute Inc., Cary NC) software. We are using well-tested scales to measure primary and secondary outcomes. Nevertheless, we will repeat the assessment of reliability of multi-item scales in this population using Cronbach's alpha, or Kuder-Richardson reliability coefficients as appropriate. We will use descriptive statistics, particularly measures of central tendency with dispersion estimates to evaluate all study measures, (e.g. mYPAS.) at each observation point, as well as averaged over all post-operative observation points. We will make appropriate transformations as needed to correct for non-normality in hypothesis testing analyses. To avoid over specification of analytic models, we will use bivariate and cluster analyses (e.g. factor analyses) to investigate variables with shared variation for the purpose of constructing vectors or composites (e.g. of demographic variables, variables related to recovery room stay, etc.) to improve statistical power and reduce degrees of freedom in models. We will *initially* use t-tests to examine treatment groups on primary (i.e. mYPAS) and secondary outcome measures (e.g. PPPM, etc.) adjusted for patient and parent covariates and independent variables as appropriate. We will use separate mixed effects linear regression models (MLM), allowing for random intercepts and time-trend variation by individual patients, to estimate treatment effects on primary and secondary outcome measures, controlled for time-invariant and time-varying covariates and will take the form: $Y_{ij} = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2ij} + \beta_3 x_{3ij} + \beta_4 x_{4ij} + \beta_5 x_{5ij} + v_{0i} + v_{1i} t_{ij} + e_{ijt}$ where Y is the quality of care, patient experience or cost of care measure for the ith patient at the j-th observation point, $\beta_0$ is the overall study population intercept, $\beta_1$ is the overall study population intervention intercept, $x_1$ is intervention effect for the ith patient at the jth time, $x_2$ is a vector of time invariate covariates, $\beta_3$ baseline population slope, $x_{3ij}$ is intervention slope for the ith patient at the jth time, $\beta_4 x_{4ij}$ is the change in slope association with the intervention for the ith patient at the jth observation point, $\beta_5 x_{5ij}$ is a vector of time variant covariates, $v_{0i}$ is the intercept deviation for the i-th patient, $v_{1i}$ is the slope deviation for the i-th patient and $e_{ijt}$ is the error term. We will use Bonferroni correction for multiple comparisons in evaluating tests of significance.

***Missing data:*** Mixed effect linear models are relatively robust to missing data and irregularly spaced observations[83]. Nevertheless, we will evaluate potential for bias in estimation of treatment effects by comparing drop-out rates, rates of 'low use' of interventions (Appendices B and C) and patterns of missing data by treatment group for primary and secondary outcomes, as well as other independent variables and covariates using t-tests for independent samples. We will use intention-to-treat analysis on the primary outcome for the full analytic sample to evaluate bias from missing data. We will consider the use multiple imputation to estimate scores on study variables as appropriate, and investigate effect of imputation method on treatment effects.

**Sex as a biological Variable**: We added this section as a response to new "*Rigor and Transparency in Research*" guidelines from the NIH. 1) The application includes both sexes; 2) we will stratify recruitment by sex to assure equal representation of both sexes; 3) we will introduce sex to all our statistical models and plan to analyze and report all results separately by sex in progress reports and publications; 3) Per NIH recommendation, since sex differences are <u>not</u> known for this intervention, sex was not considered in the power analysis for overall sample size.

***Aim specific analyses***

<u>*Aim 1. Effect of WebTIPS on children's anxiety:*</u> Using mixed effects linear modeling, but without time trends, we will evaluate intervention effects on children's anxiety, adjusted for child's temperament (EAS-TS) and parental coping style (MBSS), as well as type of surgery and child's age and sex.

<u>*Secondary Aim 1: Effect of WebTIPS on postoperative clinical recovery in the PACU:*</u> Using separate mixed effect linear models, we will assess intervention effects on postoperative pain (FLACC, FPS-R, NRS), emergence delirium (PAED), adverse effects (measured as a composite of postoperative vomiting etc.), and analgesic requirement. Models will be adjusted for surgery group, sex, and age.

<u>*Secondary Aim 2: Effect of WebTIPS on postoperative pain, maladaptive behaviors and return to normal activity:*</u> Using mixed effect linear models with time trends as noted above, we will assess intervention effects on children's pain (FPS-R), parent-reported pain (PPPM); maladaptive behaviors (PHBQ) and return to normal activities (PedQL-acute). Models will be adjusted for variables such as type of surgery group, and child's sex and age taking into account baseline measures of each dependent variable for treatment group and individual as given by the formula in section C.5 ($Y_{ij} = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2ij} + \beta_3 x_{3ij} + \beta_4 x_{4ij} + \beta_5 x_{5ij} + v_{0i} + v_{1i} t_{ij} + e_{ijt}$)

<u>*Secondary Aim 3: Effect of WebTIPS on parental preoperative anxiety:*</u> This analysis will parallel that for the child's preoperative anxiety.

*Secondary Aim 4: Effect of WebTIPS on parental satisfaction:* Using separate mixed effects linear models, we will examine intervention effect on parental satisfaction (NRC) adjusted for parents' socioeconomic status.

*Secondary Aim 5: Effect of WebTIPS on resource utilization:* We will estimate the effect of WebTIPS on resource utilization as summarized by 30-day health care spending, as measured by charges adjusted for each hospital's Medicaid cost-to-charge ratio. In the most basic specification, we will estimate the effect of WebTIPS by fitting the following model: $YY_{ii} = \beta\beta_{00} + \beta\beta_{11}WWWWWWWWWWWWWW_{ii} + \beta\beta_{22}XX_{ii} + \beta\beta_{33}WW_{ii} + \varepsilon\varepsilon_{ii}$ Here *i* denotes a patient and *WebTIPS* is an indicator variable. The coefficient $\beta\beta_{11}$ on *WebTIPS* is the main coefficient of interest, and gives the average difference in (adjusted) 30-day health care spending between the treatment group and the
control group. We will use log-linear models to analyze spending since this outcome is typically very skewed To improve precision, we can include in the estimation covariates $\boldsymbol{XX_{ii}}$, listed in C.2d in addition to basic demographic information such as age, sex, and race, the type of surgery the patient had and an indicator $\boldsymbol{WW_{ii}}$ for the site of treatment. Because our analysis of economic outcomes relies on administrative data, it has the advantage of avoiding any potential non-response issues. A limitation, however, is that we have data ibky from the study sites and will not capture care sought outside of these systems. Analyzing data from English- speaking minorities will be done as well.

*Assessing the hypothesized conceptual model:* We will use structural equation modeling to assess the hypothesized conceptual model (Figure 1), with averaged time variant observations for each construct measured in the post intervention period, and mediators and moderators as specified in the model.

*Power:* Power estimates for hypothesis testing analyses of this application were based on the ability to detect a minimally important difference between treatment groups (Cohen's d=.30) in both the primary outcome, children's preoperative anxiety, and secondary outcomes (e.g. emergence delirium etc). Based on data from the feasibility trial, to obtain a difference between WebTIPS and WebINFO of 4.3 points (pooled standard deviation = 14.99, effect size approximately .30), with $\alpha = .05$, $\beta = .80$, we would need 192 patients per treatment group. Considering all secondary outcome measures, with $\alpha = .05$, $\beta = .80$, we would need 270 patients per group for the outcome with the greatest dispersion around the mean (i.e. PPPM). To allow for 15% attrition over the course of the study a conservative sample size estimate, would be 310 patients per treatment group or a total of 620 subjects to reach the target sample size of 540 subjects.