FINAL PROGRESS REPORT

Title of Project: Relieving Anxiety in Children Undergoing Radiation Therapy through Virtual Preparation

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1. Structured Abstract

**Purpose:** The purpose of this project was to develop RadWorld, an interactive and engaging program to prepare children with cancer for radiation therapy (RT). The primary outcomes were to improve children’s knowledge about RT, decrease their anxiety, and reduce necessity of sedation for RT. Secondary objectives were to prepare the parents to increase their knowledge and decrease their anxiety associated with pediatric RT.

**Scope:** Children with cancer have misconceptions of RT and find it to be one of the most frightening aspects of cancer. This problem is compounded by the fact that many RT centers are not housed within a children’s hospital and are not staffed by pediatric specialists (e.g., Child Life). The handful of preparation programs suggest preparation is helpful; however, the programs are cost- and time-prohibitive.

**Methods:** This project involved 3 aims. In Aim 1, a beta version of RadWorld was created and evaluated by experts and patients. Results led to Aim 2, the development of child and parent versions of RadWorld, different versions for younger (4-11) versus older (12-18) patients, and different versions for consultation, simulation, and RT. Aim 3 involved a randomized controlled trial enrolling 50 participants (25 standard care; 25 RadWorld). Patients and parents completed measures of knowledge, anxiety, and satisfaction during their consultation, simulation, first RT, and second RT.

**Results:** Results from Aims 1 and 2 were presented in a paper and at national conferences. Aim 3 will soon be available once analyses are complete.

**Key Words:** Radiation therapy; child anxiety; preparation; sedation
2. Purpose

Children consider radiation therapy (RT) to be one of the most stressful aspects of having cancer. Although RT is pain-free, pediatric patients find it anxiety provoking and difficult due to misunderstandings about lasers and side effects, having to transition to an unfamiliar treatment setting and medical team, feeling intimidated by the large and noisy equipment, and being required to remain alone and motionless throughout the procedure. To ensure that children do not move during RT, sedation might be needed, which invites a host of additional risks and costs. Data indicate that patient preparation programs can improve the success of conducting RT without sedation and decrease children’s and their parents’ anxiety. A critical barrier to progress in conducting RT without sedation and decreasing children’s and their parents’ anxiety is that the current standard form of preparation – when provided at all – requires extensive time, space, funding, and personnel; healthcare resources that are increasingly in short supply.

Our goal was to improve the success and reduce the stress of RT in pediatric patients and their parents by developing and evaluating an automated, interactive, cost-efficient, time-effective, computer tablet-based, virtual world preparation program (RadWorld). Our central prediction was that RadWorld would revolutionize preparation of children across medical procedures by providing data supporting the effectiveness of RadWorld for pediatric radiation therapy.

Our objectives included: 1) developing RadWorld, an interactive, computer tablet-based, virtual world program designed to prepare children and their parents for pediatric RT; 2) evaluating the effectiveness of RadWorld on pediatric patients’ knowledge, ability to remain still, need for sedation, fear, and anxiety associated with RT; 3) determining the effectiveness of RadWorld on parents’ knowledge and anxiety associated with their child’s RT; 4) assessing children’s and their parents’ satisfaction with RadWorld; 5) quantifying and comparing the cost (time, personnel, etc.) of RadWorld to that of standard care; and 6) producing effect sizes and collecting patients’ and parents’ reactions in order to improve RadWorld for subsequent larger randomized controlled trials modified for this and other medical situations.

3. Scope

Children consider radiation therapy (RT) to be one of the most stressful aspects of having cancer. The anxiety experienced by the children and parents arises from the steps involved in the preparation and execution of RT. First, the pediatric patient will have an appointment, typically called “simulation,” to identify (via imaging) and mark the areas needing radiation. If the child will receive radiation to the head or neck, an immobilization mask is molded at this appointment to help securely restrain the head and assure that the same position is used for the subsequent repeated RT treatments. This simulation appointment lasts roughly 20-30 minutes. Typically, 1 week after the “simulation” appointment, the child attends the first RT appointment. During RT, it is essential that the patient remains motionless as any movement can lead to poor local control of the tumor and unintentional damage and injury to the unaffected surrounding tissues. RT is typically administered via a continuous daily dose; the radiation lasts only a few minutes, and the child might be in the treatment room for a total of 20-30 minutes. Treatment sessions often occur 5 days per week for 1 to 7 weeks.

Although RT is pain-free, the majority of pediatric patients find it anxiety provoking and difficult due to misunderstandings about radiation and lasers, fear of side-effects, transitioning to an unfamiliar treatment setting and medical team, feeling intimidated by the large and noisy equipment, and being required to remain alone and motionless throughout the procedure. If
children have significant distress or are unable to cooperate (e.g., remain motionless), sedation is used to ensure successful RT; the majority of children younger than are sedated, and rates of sedation for pediatric RT are increasing. Sedation introduces a host of additional medical and behavioral risks and complications and increased costs; it is far preferable to complete RT without sedation whenever possible.

Current approaches to preparation for pediatric RT and many other medical procedures are costly, time-consuming, and cumbersome. Preparation programs often involve child life specialists and other hospital staff personnel and might include role-playing the entire upcoming procedure. If the child is transitioning between facilities – as is common with RT – preparation should be conducted at each of the settings. Many of the preparation programs in practice are developed and conducted based on clinical intuition or judgment rather than the empirical literature. This might be partially because there have been few studies focused specifically on preparation for RT.

A search of the literature identified few published studies of pediatric preparation for RT. One preparation program for RT used a behavioral psychologist, who worked with each of the patients for 1 to 3 sessions of 30-60 minutes and then transferred the intervention package to a nurse and radiation therapist who continued following the protocol for multiple sessions. Part of the program included having the child meet the various medical personnel and spending time being oriented to the medical treatment rooms and equipment. The outcome measures consisted of a rating of whether the children completed 12 behavioral tasks (e.g., enters treatment area, lies motionless during RT) and whether sedation was required. Although the program was successful, the use of a psychologist and additional trained staff to perform this lengthy preparation limits the generalizability of this approach.

A second program used a play therapist and/or nurse, who were first trained in developmental issues. The preparation intervention included rehearsal, emotive imagery, and positive incentives for the patient in the various treatment settings on several occasions prior to the actual RT. The program had some success but the authors indicated substantial resources were required to conduct the extensive intervention and that “consideration needs to be given to environmental constraints…” to provide “cost-effective health care…”

A third program involved a preparation package consisting of explanation and instruction by the nursing coordinator, a visit to the radiation unit to meet the clinical personnel and view the location and equipment, and an extensive intervention with an art therapist focused on lying still, remaining alone, and wearing a mask if necessary. The study lacked sufficient outcome measures to determine success, and here again the cost and time requirements were significant barriers to widespread dissemination of the intervention.

A fourth program involved a study of 79 children who were randomized to a preparation video and battery-operative moving Barney doll treatment condition or a control condition (i.e., cartoon video and non-animatronic Barney doll). Outcome measures included patient observational distress, sedation, and heart rate; and parent self-reported anxiety. Although parents in the treatment group were less anxious and the children in the treatment condition demonstrated greater reductions in heart rate from baseline to simulation, there were no group differences on observational distress or sedation rates. Although the intervention was brief and practical, results suggest that the intervention was too weak to impact children’s distress or sedation rates.
Results from the handful of studies of preparation for RT and retrospective analyses of preparation programs suggest that there can be positive benefits with a preparation program. All of the previous treatment approaches except one were arguably cost- and time-prohibitive and surplus finances, staff, and space are becoming increasingly scarce in healthcare. It should be noted that these costs can be recouped via savings through decreasing the frequency of sedation. Success of the interventions is difficult to ascertain without a control group; only one study included a comparison condition. Unfortunately, the weak intervention in this study was not superior to standard care. None of the studies included comprehensive assessments of the key constructs. For example, observational measures of children’s behavioral cooperation and distress as well as children’s subjective report of anxiety should be central indices considered in RT preparation evaluations. Given the dearth of studies of preparation for RT, qualitative methodology might be critical to identify additional considerations with this population. Interviews with patients might highlight unforeseen patient-centered areas of concern and need for intervention. In short, there is a need to collect finer-grained quantitative and qualitative data to maximize the relevant information and optimize preparation for pediatric RT.

A critical barrier to progress in improving the success of conducting RT without sedation and decreasing children’s and their parents’ anxiety is that the current standard form of preparation – when provided at all – requires extensive time, space, funding, and personnel; healthcare resources that are increasingly in short supply. Our project improves scientific knowledge, technical capability, and clinical practice by providing evidence-based pediatric preparation in a virtual world iPad Air® platform. The extant literature indicates that in order to minimize anxiety and optimize procedural adherence, children and adolescents should be prepared by providing them a) accurate sensory and procedural information, and b) coping skills to use during the procedure. When transitioning across healthcare providers and settings – as is common in RT – it can be cost- and time-prohibitive to provide the necessary preparation for children. A virtual environment can accomplish all of the goals of pediatric procedural preparation in an engaging and practical format.

When designing preparation programs, it is important to ground the intervention in theoretical or conceptual frameworks. One of the earliest theories regarding preparation posited that advanced information allows a child to ruminate, cognitively rehearse, and habituate to the event resulting in decreased distress during the actual event. This was termed “the work of worrying.” Taking a similar cognitive perspective, self-regulation theory suggests that preparation serves to increase the congruence between the expected and actual experience and allows the child to better prepare (e.g., to select coping strategies) for the procedure. Developmental theories might also be used to help guide preparation approaches. Tied to Piagetian theory, children in the preoperational stage (2-6 years old) should receive simple and descriptive information, such as what will transpire in the treatment room and what they might see, smell, and hear. 7- to 12-year-olds in the concrete operational stage might understand analogies, how long aspects of the procedure will last, and sensations (e.g., warm sensation) linked to procedural steps. Adolescents (13- to 18-year-olds) in the formal operational stage can appreciate information about how the procedure will impact their disease and body as well as future-oriented information. Vygotsky’s theories also provide guidance on preparation programs. For example, an appropriate preparation program should be slightly challenging and provide sufficient information to allow children to cope with a procedure that otherwise might have been beyond their abilities. Piaget’s and Vygotsky’s theories also emphasize active learning, which is enhanced by an interactive game. These
theories provide a solid framework for designing RadWorld to address the needs of children of varying ages.

Qualitative inquiry is used to generate an understanding of individuals’ experiences within a specific context. Quantitative inquiry is used to objectively test hypotheses and generalize findings from these tests to a broader population. Given the goals of the current study—to (1) develop an understanding of pediatric patients’ experiences with RT in order to develop a virtual world game intervention, (2) assess the extent to which the developed game matches patients’ experiences and will be useable by all pediatric RT patients, and (3) test the efficacy of the intervention—it was necessary to mix qualitative and quantitative methods to achieve the project goals. It is important that the purpose of each aim match the methodological procedure selected. Based upon the stated project aims, therefore, this overall procedure constituted a sequential exploratory mixed method design with core qualitative designs proposed for aims 1 and 2 (interviews to develop and refine RadWorld) leading to a core quantitative design proposed for aim 3 (randomized controlled trial). Although core methodologies have been selected to match the purpose of each aim, we used both qualitative and quantitative methods and analyses in pursuit of achieving each aim’s objectives.

4. Methods

Aim 1 and 2. Develop and Refine RadWorld

Design. This phase of the project required inductive analysis and involved qualitative approaches to define and create the RadWorld content, character, and interface. Our approach involved solicitation of feedback from patients and parents via semi-structured interviews in order to refine the game blueprint to ultimately produce a beta version of RadWorld. The interviews resulted in actionable tasks to improve RadWorld, including but not limited to changes to character sound and appearance, script, situations addressed within the game, and how participants interact with the game.

Participants. Pediatric participants of varying ages and their parents were involved in the development and refinement of RadWorld. Specifically, 4- to 18-year-olds who recently completed RT and their parents from CHOA Cancer Center participated.

Measures.

Family Background Information. Parents completed the Family Information Form, which assessed demographic information (e.g., child’s age, gender, ethnicity, race.

Procedure.

RadWorld Development and Refinement. Based on our preliminary data, standard practice in our oncology settings, and the expertise and experience of our multidisciplinary research team (e.g., pediatric oncology physicians, pediatric and developmental psychologists, child life specialist, computer technicians, research design and analysis expert), we developed concept art, storyboards, and scripts that composed the RadWorld blueprint. The concept art guided the visual design and expressive direction of the 3D rendered environments, non-player characters (NPCs), and the player avatars (stylized 3D representations of the player). The flow of the storyboards mirrored the procedures of RT. Within the storyboards, the patient walked through the Winship Cancer Institute RT procedure, including the simulation, molding of the mask if necessary, and then returning for the actual RT session. The initial blueprint included character designs for the patient avatars, a “guide” who will accompany the patient throughout
the storyboard, and medical staff of the Winship Cancer Institute who will provide information to the patient. In addition, the storyboards included a game in which the patient earns points for remaining motionless during simulation and RT.

Based on feedback, we incorporated videos of child actors undergoing both simulation and RT so that the patient could observe both animated images and characters as well as actual videos. In addition, upbeat music was incorporated into the background to lighten the mood during RadWorld. We incorporated multiple characters that the child could select as with both female and male narrators. Our piloting informed the decision to have slightly different scripts for younger (4-11 years old) and older (12-18 years old) patients, with the older patients receiving more sophisticated information about the simulation and RT procedures. Most importantly, Aim 1 and 2 interviews informed the research team that it is critical to also prepare the parents for RT and to coach their children. Thus, a separate RadWorld program was developed for parents that involved similar components as the child, but included tips for how the parent could help the child. The parent also played the same game so that the parent and child could share their scores and experience with attempting to remain motionless. In addition, the research team decided that the RadWorld program should be completed by patients and parents prior to each of the 4 appointments (consultation, simulation, first RT, second RT), and slightly different versions of the game were created for consultation, simulation, and RT.

**Aim 3. Evaluate the Effectiveness of RadWorld for Pediatric Radiation Therapy Preparation.**

**Design.** We used a randomized controlled trial (RCT) to test Aim 3 hypotheses. Our RCT adhered to the guidelines detailed by the CONSORT statement.

**Participants.** We proposed to enroll 50 participants. At the time of this report, we have enrolled 51 4- to 18-year-old patients with cancer receiving RT and their parents.

**Measures.**

**Family Background Information.** Parents completed the Family Information Form, which assesses demographic information. This form queries about the parent’s relation to child, gender, age, ethnicity, race, education, and income; and child’s age, gender, ethnicity, race, and relevant medical history (relatives who have received radiation, type of cancer, whether child will receive radiation to the head or neck).

**Child and Parent Knowledge.** Both children and their parents completed the Radiation Therapy Knowledge Interview (RTKI; child and parent versions) at baseline (prior to the consultation meeting) and post-radiation (following the first RT procedure). The interview contains 9 open-ended questions about RT (e.g., purpose of simulation, side-effects of radiation treatments, reason that the child must remain still during RT). The questions were created by our team and were circulated to oncology staff for revisions and refinement. All child and parent responses to questions were written down so that a second researcher can independently score a randomly selected 20% of the responses. Any discrepancies in scores will be resolved by a third researcher.

**Child Fear and Anxiety.** Given that fear and anxiety are subjective and internal experience, multiple measures were used. Children provided self-reported ratings of fear pre- and post each procedure (consultation, simulation, RT visit 1, RT visit 2).
Self-report for 4- to 11-year-old patients was assessed via the Children’s Anxiety and Pain Scales (CAPS). The CAPS-Fear/Anxiety contains a set of five drawings of children’s faces expressing increasing levels of fear/anxiety. The CAPS is widely documented in pediatric procedural distress research and practice, is easy to use, and has good reliability and validity. Data suggest that children as young as 4 years of age can report internal distress using face scales.

Patients 12 to 18 years old, parents, and the radiation therapist provided ratings of children’s fear and anxiety with 100mm visual analog scales (VASs) at the same time points as the children. VASs are commonly used in pediatric procedure research, are quick and easy to use, and they do not result in clustering of scores as is common with categorical-type scales. In a review of acute procedural pediatric measures, VASs were rated “well-established,” the highest rating. Medical staff and parent ratings are important given that adults often make decisions as to whether or not to intervene (e.g., sedation, comforting efforts) in children’s medical distress.

Parent Fear and Anxiety. Parents rated their own fear and anxiety using a VAS at before and after consultation, simulation, first RT, and second RT. In addition, the simulation technician or the radiation therapist evaluated parent anxiety using VASs prior to and after simulation, first RT, and second RT.

Cooperation and Stillness. The Simulation and Radiation Therapy Task Analysis is a measure established in a prior study of preparation for pediatric RT. The authors detailed 12 separate behavioral steps (e.g., “Child enters the examination or treatment room”; “Child lies motionless in position…”) required of children during simulation and RT. A research assistant observed each participant from the observation rooms – which has a window and closed circuit television screens – during both simulation and RT and recorded how many steps were completed.

Sedation. A research assistant will record whether each patient enrolled in the study required sedation or not in order to complete RT. As over 50% of young patients (approximately 4 to 7 years old) at Winship Cancer Institute require sedation, we expect there to be sufficient variability in our sample to find differences between groups.

Satisfaction. At the conclusion of the first RT, the Treatment Satisfaction Inventory (TSI) was used to evaluate children’s, parents’, and radiation therapists’ satisfaction with RadWorld as well as standard care. The TSI is a 10-item measure querying participants’ about their satisfaction with the procedural preparation. Each question is answered from “Strongly Agree” (1) to “Strongly Disagree” (5). The TSI was based on the Treatment Evaluation Inventory – Short Form (TEI-SF), a validated measure of parent and staff satisfaction of interventions for children. Given the high reading level of the TEI-SF and that it is not specific to medically-related interventions, the TSI was developed. In a prior project evaluating an interactive computer preparation program for pediatric immunizations, the TSI demonstrated strong internal consistency, with a Cronbach’s alpha of .94. In the current project, Cronbach’s alpha will be used to evaluate the internal consistency of the TSI and to determine if any items should be eliminated when computing the final score.

Procedure. The CHOA Cancer Center staff member informed all eligible parents of children about the study via the phone. Thus, parents and children could arrive 15 minutes early to the consultation appointment to complete the consenting, baseline measures, and study procedures prior to the medical appointment. At the Center, the researcher described study protocol and obtained parent consent and child assent to participate, administered the Family Information
Form, and helped the parent and child complete the knowledge interview and anxiety measures. Families were randomized to either RadWorld or standard care, which are described in detail below.

**Standard care.** Following completion of baseline measures and knowledge interview at the consultation visit, children assigned to standard care were prepared for the upcoming RT in line with standard protocol. This might involve a Child Life specialist depending on availability and whether the child was inpatient in the Children’s hospital or not.

**RadWorld.** Following completion of baseline measures and knowledge interview at consultation, children and parents assigned to RadWorld were provided the iPad Air® RadWorld tablets and headphones and they completed the programs. RadWorld allowed the child to virtually see and experience simulation and RT and meet the oncology staff via first- and third-person perspectives. Guides within the game explained the procedures and lead the child through the adventure. A game is embedded within RadWorld to reinforce the patient for remaining still throughout simulation and RT. This game required the child to hold the iPad still in order to balance animated stacks of balls on islands. If the child moved, a ball would wobble and fall into the water. Points could be earned and lost depending on movement. In addition, there were distractions (e.g., sharks in the water, birds in the air). The game informed the child that, like the game, the child must hold still during RT and battle both distraction and boredom. Parents completed a parallel version of RadWorld that informed the parent about the medical procedures, provided tips on how to help their child, and allowed the parent to play the same game.

All children and parents assigned to RadWorld completed the RadWorld game prior to consultation, simulation, first RT, and second RT. Different versions of RadWorld were loaded depending on whether the family was receiving consultation, simulation, or RT.

In line with oncology protocol, approximately 1 week following the consultation visit, families in both conditions returned for their simulation appointment. At this appointment, the researcher met the child and parent in the waiting room and helped them complete the pre-simulation measures. The radiation therapist – blind to study hypotheses and participant condition – also completed ratings of child and parent fear. During simulation, the researcher completed the Simulation and Radiation Therapy Task Analysis. At the conclusion of the simulation procedure, the child and parent completed the post-simulation measures of anxiety. The radiation therapist also completed ratings of child and parent simulation procedure anxiety.

Consistent with protocol, approximately 1 week following simulation, patients and their parents returned for their first RT appointment. Similar to the protocol for the simulation procedure, the parent and child completed pre-RT measures. Again, the radiation therapist rated the child’s and parent’s anxiety. The Simulation and Radiation Therapy Task Analysis was completed during RT. Following RT, the child, parent, and radiation therapist completed measures of child and parent RT anxiety. In addition, the post-knowledge interview was completed with the child and parent and satisfaction measures were completed by the child, parent, and RT technician. Typically, the very next day, the child and parent returned for the second RT. The same protocol was followed at this appointment except the knowledge interview was not conducted.

**Data Analyses, Anticipated Results, and Interpretation.**
Preliminary analyses will be conducted to determine whether demographic variables (e.g., age, ethnicity) and type of cancer are related to baseline knowledge, anxiety, cooperation, movement, and sedation. Specifically, to examine gender differences, t-tests will be used, and Analyses of Variance (ANOVAs) will provide a comparison across ethnicities and races on the dependent variables. Pearson product moment correlations will reveal any relations between age or family income and outcome variables. Baseline measures of knowledge will also be compared between the conditions with a t-test to ensure that the randomization process was effective. A 5 (Child Life specialist) x 2 (condition) ANOVA with follow-up planned comparisons will compare the 5 Child Life specialists on the dependent variables across conditions. If any of these analyses result in significant findings, they will be considered as covariates in subsequent analyses.

Primary analysis will compare RadWorld and standard care on the dependent variables. First, we will examine the effectiveness of RadWorld for increasing children’s and parents’ knowledge of the RT process. A 2 (condition) x 4 (time) repeated measures ANOVA will be conducted to examine the main effect of difference between conditions, the main effect of changes in knowledge over time, and the interaction of changes in knowledge over time between RadWorld and standard care participants. Significant omnibus ANOVAs will be followed up with planned comparisons between time phases and conditions.

It is expected that the children and parents in the RadWorld group will demonstrate greater knowledge than the children and parents in standard care. Specifically, it is expected that no differences will be found at baseline, but both groups will improve in knowledge when tested at simulation and RT; however, it is expected that participants exposed to RadWorld will have a greater improvement in knowledge than participants receiving standard care preparation.

Similar findings are expected with the fear and anxiety analyses. Consistent with the literature, it is expected that children and parents will be highly fearful about RT at baseline. We expect that standard care preparation will be somewhat helpful in reducing fears, but that RadWorld will be significantly better at alleviating children’s and parents’ fears associated with simulation and RT. Similar patterns are expected for results with measures of children’s and parents’ anxiety.

ANOVAs will be used to compare RadWorld and standard care on children’s cooperation and children’s need for sedation.

It is expected that the children exposed to RadWorld will have greater cooperation at simulation and RT, more time remaining motionless at simulation and RT, and require fewer sedations for RT than children receiving standard care preparation.

We expect that we will find significant mean differences (t-test) in satisfaction, cost, and time between RadWorld and standard care at one-week post RT with both patients and parents being more satisfied with RadWorld than standard care.

**Limitations.**

As is common with clinical studies, there was significant variability within and across participants. For example, some patients had several weeks between the consultation visit and the simulation visit and others had consultation and simulation within the same visit. In order to manage this issue, the research team decided to enroll additional participants beyond the proposed 50. Current, we have enrolled 51 and intend to continue enrolling for 1 month. Another challenge is that some participants were prepared in advance via searching the internet and others
had no information. It is expected that the randomization will resolve this issue prior to data analyses. The most significant issues were problems with technology and findings from Aim 1 (development of RadWorld) necessitating significant changes in Aim 2 (refinement and finalization of RadWorld). Specifically, the RadWorld program is an app on the Apple platform. However, when there were changes to the Apple operating system it required changes to the app. Aim 1 findings resulted in several versions of RadWorld being created (i.e., child and parent versions; consultation, simulation, and RT versions). This slowed down completion of Aim 2 and delayed the start date for Aim 3.

5. Results
As detailed above, Aims 1 and 2 were completed. Results and information about this aspect of the study has been published and presented at national conferences (see below). However, the delays has resulted in only recent completion of the proposed enrollment of 50 participants in the RCT (Aim 3). As described above, additional participants are currently being enrolled. Thus, Aim 3 analyses have not been conducted and results from Aim 3 are not yet available.

6. List of Publications and Products

