Evaluating Virtual Reality as an Adjunct in Procedural Preparation for Magnetic Resonance Imaging (MRI)

A Pilot Project to Reduce Costs while Improving Quality, Access, Efficiency and Patient Experience in Medical Imaging at BC Children's Hospital

RESEARCH PLAN

Document History

Ver.	Date	Author	Description of Changes / Comments
1.0	Feb 20/19	C.Stunden	*1st Draft*
2.0	Jun 06/19	C.Stunden	- Updated methods following Phase 1

Contents

1.0 Project Team

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2.0 Abbreviations

3D	Three-dimensional (environments)
BCCH	British Columbia Children's Hospital
CLS	Child Life (Specialists)
IPD	Interpupillary Distance
LoS	Length of (Hospital) Stay
MRI	Magnetic Resonance Imaging
PDSA	Plan-Do-Study-Act cycle
RA	Research Assistant
Short-STAI	Short State-Trait Anxiety Inventory
TCPS-2	Tri-Council Policy Statement
TRL	Technology Readiness Level
VR	Virtual Reality

3.0 Introduction

Operational Context

Over 4500 patients undergo magnetic resonance imaging (MRI) at BC Children's Hospital (BCCH) each year (**Table 1**). In 2017/18, the waitlist for sedated cases reached a significant point where some patients were forecasted to endure a wait of up to two years for their scheduled appointment. To address this, the Hospital launched a coordinated strategy that included increased operational capacity and funding for clinical and support services. Child Life Specialists (CLS), who are specially trained individuals that work with patients and families to help prepare patients for the MRI procedure, were amongst these resources. CLS are considered a key factor in enabling some patients to undergo imaging without the use of sedation, where otherwise it may have been indicated due to pre-procedural anxiety and high probability of non-compliant behaviors. While the Hospital has invested efforts and resources in improving access to CLS, capacity limitations exist, and there are socioeconomic costs of only having this support available on-site at BCCH. The Project Team intends to develop a standardized preparatory adjunct delivered using virtual reality (VR) technology, and explore the effectiveness of this tool. Ultimately, our goal is to explore the potential for this adjunct to complement the existing efforts of the Medical Imaging Department and Child Life Specialists to improve access, quality, efficiency, and patient experience at BCCH. A core component of this project is to also assess the economic impacts of this solution.

Table 1. Magnetic Resonance Imaging statistics from BC Children's Hospital (BCCH) Child Life Department, Fiscal Year 2018/2019.

	Q1	Q2	Q3	Q4 (as of Feb 22, 2019)
Non-Sedated	644	576	644	530
Sedated	443	475	483	487
TOTAL	**1,087**	**1,051**	**1,127**	**1,017**

Pre-procedural anxiety and non-compliance

Fifty percent of pediatric patients experience elevated anxiety and distress prior to new medical procedures.[1] In children, pre-procedural anxiety has been found to be a function of numerous factors, including: caregiver anxiety, temperament, age, previous medical encounters, a fear of separation from parents, unfamiliar environments, a loss of control, as well as coping with unfamiliar routines, instruments, and procedures.[1]

The issue of pre-procedural anxiety is critically important because it not only impacts patient experience and is associated with psychological and physiological distress, but it can affect the efficiency of medical procedures, length of stay in the hospital (LoS), and resource utilization – all of which have economics impacts to both families and the health

system. During medical imaging procedures specifically, anxiety can cause non-compliance or unintentional movement which often leads to failure to complete the procedure or poor image quality, necessitating multiple attempts or the use of sedation to achieve the desired quality of imaging. The impact of sedating a patient has several downstream effects, including the increased potential for adverse events, as well as the need for specialized clinical staff (i.e. Anesthesiologists, Post-Anesthetic Care Nurses, etc.), medications, and lengthier post-procedural monitoring. Studies have also indicated an increase in negative post-procedural outcomes when patients are sedated, such as increased pain perception, increased pharmaceutical consumption, reductions in sleep and eating, generalized anxiety, and greater dissatisfaction. [2–8]

Child Life Magnetic Resonance Imaging (MRI) Simulations

The literature suggests that approximately 50-to-75% of all patients who undergo MRI exams at pediatric hospitals are sedated.[9] CLS reduce sedation rates by exposing pediatric patients to MRI simulations, thus alleviating symptoms of pre-procedural anxiety and distress. MRI simulations include mock scans that appear and sound identical to the real MRI, but lack the magnet, and thus functionality to take images. It's suggested that preparation programs like this can reduce sedation rates by about 20% (those who are eligible, recruited, and successful).[9]

Between November 2017 and January 2019, approximately 377 of the pediatric patients attending BCCH for MRI were eligible and referred for preparation with a CLS. Of the patients who proceeded with simulation (N=344), 82% were able to successfully be converted to a non-sedated MRI (**Table 2**).

Table 2. Simulation statistics from BC Children's Hospital (BCCH) Child Life Department, Nov2017 – Jan2019.

	Non-Sedated MRI	**Sedated MRI**
Passed Simulator	283	8
Failed Simulator	0	53
TOTAL	**283**	**61**

It is evident from the literature and our own hospital data that CLS preparation is effective in reducing anxiety, non-compliant behaviors, and sedation rates.[9] At BCCH, children under the age of 7 who wish to have a non-sedated MRI must pass an MRI simulator with a CLS. However, the patient's ability to prepare with a CLS can be impacted by geographical barriers and socioeconomic status. Transportation barriers have been repeatedly identified in the literature and by parents as a source of unmet health needs for children in both rural and inner-city populations.[10] This is significant, because if a caregiver cannot get their child to the MRI simulation, they miss the opportunity for a non-sedated MRI, and consequently that increases resources and the risk for complications.

How can digital intervention help to improve access?

Given the effectiveness of CLS preparation programs on the success of non-sedated MRI[9] and the promising evidence that immersive technologies can effectively reduce pre-procedural anxiety and non-compliant behaviors,[11,12,21,13–20] we sought to make quality improvements and adjustments to the MRI experience by developing and evaluating a multisensory, realistic, and vivid virtual preparation program. Immersive VR experiences create a three-dimensional image that appears to surround the user. Complimented by high visual and sound quality, motion sensors, and speech recognition, VR can take input from users to interact with a highly realistic and vivid virtual environment. As such, our virtual MRI preparation program has the capacity to expose patients to experiences that mimic medical imaging procedures without the financial and physical limitations associated with traditional in-person simulation. Finding effective solutions for patients with geographical barriers and lower socioeconomic status are worthwhile in reducing sedation rates, increasing cost-savings and improving hospital efficiency.

Project Purpose

The goal is to improve access to effective preparatory resources for non-sedated MRI. Before initiating this project, we conducted a literature review to identify the existing evidence that supports the potential benefits and risks of immersive technologies used for preparation of medical procedures in general. Further, to help discover where and how the program could work, we developed an alpha prototype (V0.1) of the MRI environment. From these tasks, we observed the basic principles of developing a virtual simulation program for medical procedures, of which will inform this project.

This project plan focuses on outlining the procedures for:

1. Developing a VR simulation of the MRI experience at BCCH; and
2. Evaluating the effectiveness of the VR simulation in preparing patients for a **simulated** MRI experience; and
3. Modelling the costs and benefits associated with VR as compared to current programs, to estimate the impact and overall cost-benefit of this new intervention.

4.0 Methods

4.1 Key Question(s)

1. Can a virtual reality simulation effectively prepare children for a non-sedated MRI?

2. What are the economic and performance impacts of integrating this innovation into clinical operations? (at the hospital and health-systems level).

3. What are the estimated socioeconomic benefits to patients and families of this innovation, in comparison to the status quo model?

4.2 Objectives and Hypotheses

Phase 1: Design and Development of the Virtual Reality Experience

1. Work with an interdisciplinary team to collaboratively develop an engaging prototype (V1.0) that models the MRI environment and experience at BCCH.

Phase 2: Technology Evaluation and Comparative Assessment

2. Evaluate the effectiveness in pre-procedural preparation through a comparative assessment against other modes of delivery currently offered at BCCH – including pre-procedural instructional booklet, and mock MRI with CLS.
    a. *Hypothesis:* There will be differences in outcomes between the virtual reality group and the booklet group.
    b. *Hypothesis*: There will be no difference in outcomes between the mock MRI and virtual reality simulation groups.
    c. *Hypothesis*: Children will prefer the virtual reality and simulation exercises to booklet preparation.

Phase 3: Economic Evaluation and Impact Modeling

3. Evaluate costs and benefits of the VR solution and status quo; and conduct economic modelling on the prospective impact of operational integration.

4.3 Phase 1: Design and Development of the Virtual Reality Experience

Objective 1: Work with an interdisciplinary team to collaboratively develop a prototype that simulates the MRI environment and experience at BCCH in VR.

The media will be co-developed with a multidisciplinary team of stakeholders, including patient and family partners. Considerations for designing the resource have been informed by Gitlin (2013).[22] In principle, the developed media will integrate an animated character that will guide the user through a series of tasks. The user will be encouraged to pivot, rotate, and semi-independently explore the virtual environment. The virtual environment will be created using any combination of 360 video and UNITY, a cross-platform game engine used for 3D environments (**Table 3**).

Table 3. Considerations for designing the VR media, adapted from Gitlin (2013).[22]

Domain	Program Elements
Target of Intervention	Individual Family and social network
Area Targeted	Reduce anxiety and non-compliant behaviours that necessitate sedation Increase knowledge about the MRI procedure and environment Improve skills required for successful MRI (e.g. holding breath)
Delivery Technique	Multiple iterations, tailored to children of different age groups (4-12 and 13-18 years) and their caregivers Needs assessment driven
State of intervening	Prevention of sedation
Delivery mode	Virtual Reality Booklet Mock MRI
Dose and intensity	Frequency of contact (TBD) Length of time engaging (TBD)
Immediate and potential delivery setting	Hospital, clinic, or medical office (immediate) Mobile technology (immediate) Home (potential) Community (potential)
Characteristics of interventionists	Self-Guided delivery
Potential funding streams to support the intervention if proven effective	Costs associated with training (TBD) Costs associated with technology (TBD) Cost benefit to healthcare systems (TBD)

We have elected to use Google Pixel and MERGE VR as primary deployment hardware due to its balance of quality and affordability, given this specific use-case. The use of a mobile phone to view the content will allow for use in more affordable VR mechanisms in the future (i.e. Google Cardboard, a self-assembly cardboard version of a VR viewer), and easy transport to community or home-based settings (i.e. Cardboard mechanism is sent with instructions to end-users to assemble and launch app on their personal device at home). Movement throughout the platform will be facilitated through one (or a combination) of the following options, decided in collaboration with stakeholders:

1. Continuous Motion: the user has no control of travel
2. Magnetic Switch: the user can be stopped and started using a toggle switch
3. Bluetooth Controller: the user is in direct control of forward and backward travel

The program will be designed and continuously evaluated using the Plan-Do-Study-Act (PDSA) cycle, and created in the steps following the Technology Readiness Scale (TRL).[23] Specifically, our project focuses on progressing through phases 2 through 5 (**Figure 1**).

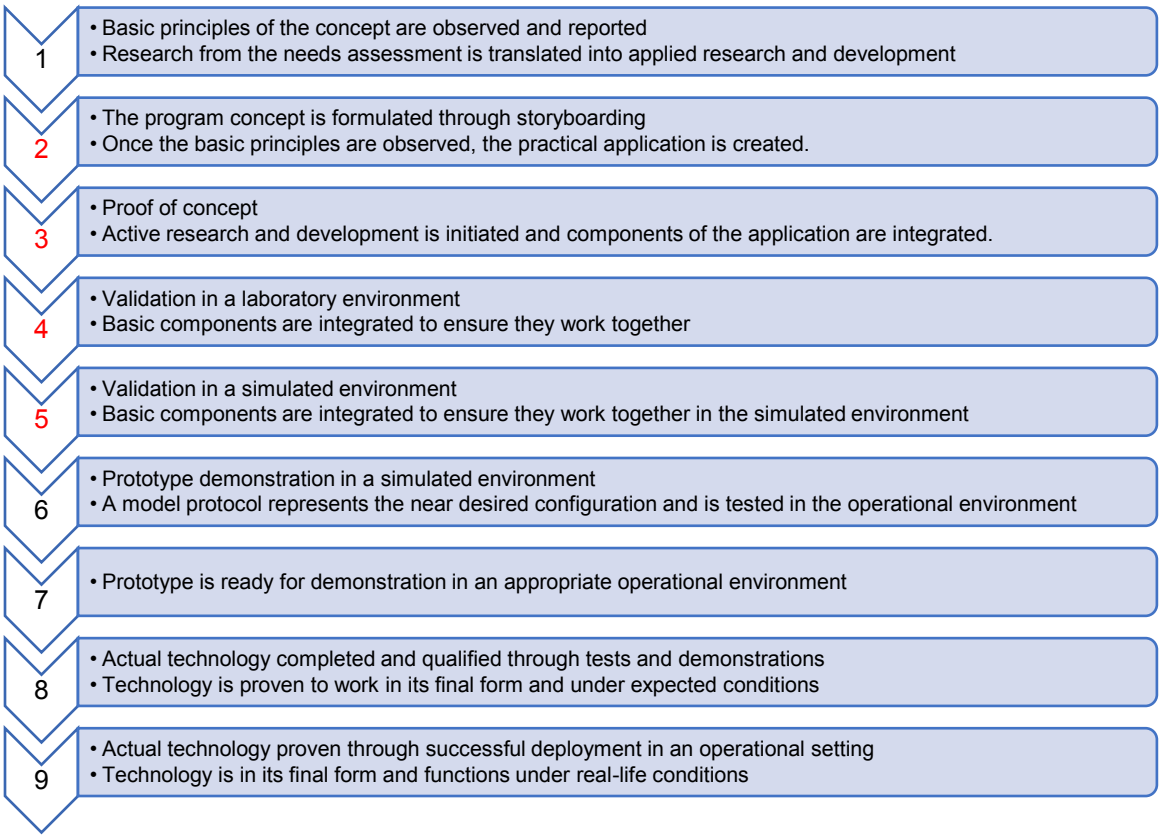

Figure 1. Technology Readiness Level scale.[23]

The Virtual Reality Simulation

The VR intervention is underpinned by experiential learning and social cognitive theory, such that experience and accomplishments obtained through observation of successful performance and simulation in the VR experience will encourage imitation and reinforce success in the real MRI experience.[24] The VR tour will introduce and explain the preparation and procedure of MRI scans within the BCCH medical imaging centre. Users will be able to turn, pivot, and explore the virtual room. The video will be at an appropriate length to ensure the pace can be followed by younger children, but will allow users to pause or stop at any point, to reduce the potential for motion sickness, headaches, or dizziness.[17]

Patients and families will be directly involved in the development of the resource to ensure the content is effectively tailored, relevant, and generalizable to practice settings. An advisory group will be developed to help guide this project and support content development and clinical validation – group membership includes Child Life Specialists,

Physicians, Nurses, Psychologists, Health Literacy Specialists, Media Developers, and others (to be determined).

Any medical staff depicted in the virtual world will be dressed in common professional attire to improve realism. An animated character will guide the user in the tour. Filming will be dependent on access to resources, but will likely be carried out using GoPro Fusion (360-degree camera) in the medical imaging facility at BCCH. The video components will then be stitched together, and the VR tour will be available using a variety of low-cost VR systems, accessible through a public-facing website. Since filming will occur in the hospital, it may occur over multiple iterations to ensure that patients and/or medical records are not inadvertently filmed.

To promote the self-guided nature of our proposed delivery, the virtual interaction will begin with a tutorial explaining how to use the application. When ready, users will be invited to be virtually guided through the MRI procedure. They will be able to pause the experience at any time. The content may include experiences such as:

1. Entering the medical imaging facility
2. Preparing for the scan (e.g. changing into a gown, checking height/weight, removing metal)
3. Additional information will be provided about the procedure, including:
    - What MRI is and the sounds it will make
    - The importance of staying still
    - What intravenous contrast (GAD) is
    - What equipment to expect
        i. Knee coils
        ii. Head coil
        iii. Hand coils
        iv. Foot coils
        v. Leg coils
        vi. Body coils
        vii. Shoulder coils
        viii. Seatbelts
    - Other information, as identified
4. Receiving numbing cream, and an IV
5. Choosing if they want to be accompanied during the scan
6. The two MRI rooms
7. The opportunity to freely explore the room and medical devices, such as the MRI machine, the patient table, the murals on the walls, types of coils, and straps.

The character will also guide the user through the MRI sequence. Content may include:

1. Wearing ear protection and headsets
2. Watching a movie
3. Talking to the MRI Technologist out loud
4. Using the emergency call bell, if required
5. The control room where the Technologist goes
6. Laying on the table and being strapped into place using the coils and seatbelts
7. Entering into the bore of the MRI machine

8. The red light used to center the patient's body for the pictures
9. Starting and completing the scan (i.e. wait a pre-designated amount of time inside the bore, before easing the patient outside the scanner).
10. Receiving intravenous contrast liquid (if applicable)

4.4 Phase 2: Technology Evaluation and Comparative Assessment

Objective 2: **Evaluate the effectiveness of the VR simulation in preparing patients for MRI, and compare to other modalities (i.e. booklet, simulation with CLS).**

Protocol for Evaluating the Virtual Reality MRI Simulator

The goal of Phase 2 is to evaluate the effectiveness of the intervention on the basis of its ability to prepare patients and families for the MRI procedure. To do so, this phase will establish evidence to investigate whether the VR intervention can be implemented to reduce anxiety and efficiently prepare children for non-sedated MRI scans. Our needs assessment has identified that new accessible behavioral interventions are both needed and desired to alleviate the anxiety and lack of preparation necessitating sedation during medical imaging with children who live afar, who are not mobile, and who need extra practice. Virtual preparation is a promising practice that has been found to be safe, feasible, and acceptable in multiple clinical care settings.[12,13,16,20,25]

The project evaluation plan consists of comparing the current modes of delivery through an objective assessment of movement and inquiry into the acceptability and utility of the intervention components, including potential barriers to adherence or behavioral change that could have unintended consequences. This information will help to generate knowledge that can be used to refine the current prototype and support future innovation in this domain at BCCH (Phase 4, not included in this proposal).

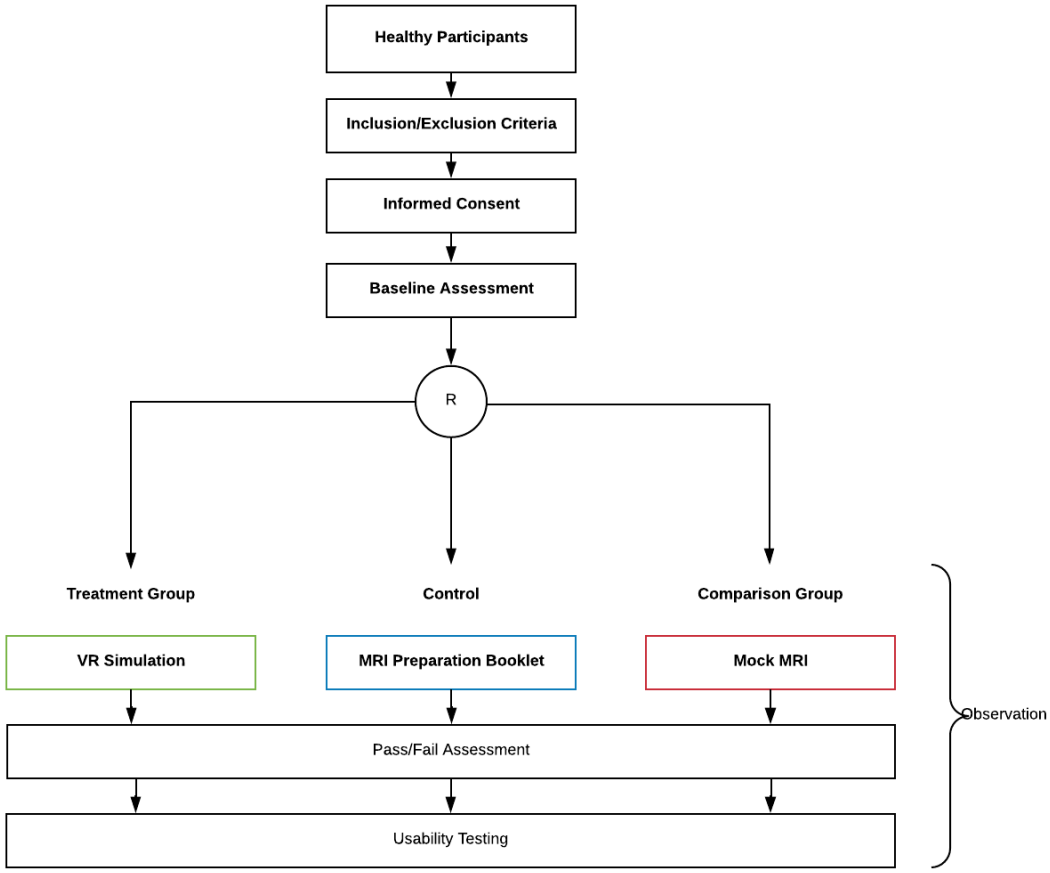

Figure 2. Evaluation design.

The recruitment strategy has been informed by the literature on recruitment in pediatric research settings.[26–28] The design and expansion of the recruitment strategy has enacted as a response to the low enrollment rate arising from traditional strategies (posters that we had initially proposed). Participants will be recruited through:

- **Advertisements, flyers, internet postings and/or social media through the Digital Lab website (www.bcchdigital.ca), the BCCHRI website, social media, and through hospital and community recruitment boards.** Community focused recruitment will include flyers and posters distributed to various public places such as local supermarkets, children's stores, playgrounds, clinics, and coffee shops with applicable advertisement boards for community postings. The use of Facebook Ads has been emerging in the literature as a recruitment strategy. A typical ad will be comprised of a succinct description about the research with a hyperlink that directs the Facebook user to the recruitment poster with more information about the study's eligibility criteria, compensation, and enrolment instructions.[29] Our ad was designed following the recommendations of Wozney et al. (2019) who recommend in video format. Our content was selected to appeal to caregivers of children between 4 to 13 years. Audience targeted fields in the Facebook ad manager will be selected to show ads to users with specific interests and demographics (e.g. children between the ages of 4 and 13, located in

Vancouver, BC). Facebook analytics will be used to track actions related to the ads.

- **Direct recruitment of potential study participants through clinical staff at the Hospital (BCCH) talking with their own or clinic patients about the study and/or contact between the study team and the potential participants on the phone or via email.** Any initial contact made by our study will be by someone who is thoroughly knowledgeable about the study, able to answer questions, and trained in the voluntary nature of the research participation.

Parents/participants will be invited to initiate participation in the evaluation by emailing or calling the Research Manager (chelsea.stunden@ubc.ca; 604-875-2345 ext. 6512). The study parameters will be reviewed with the prospective participants, and informed consent will be emailed to the participant. Verbal consent (provided over the phone or through email) will be obtained to initial allocation, and written informed consent (parent or guardian) and assent (participant over 7 years) will follow in-person. Participants will be reimbursed for parking and provided snacks and refreshments during inactive segments of the evaluation process. A $20 remuneration will be provided to each participant for their time volunteering in the study components.

A minimum of 93 participants (31 participants per group) aged 4-to-13 will be recruited through convenience sampling, consented, and randomized by staff to one-of-three preparation programs (VR, mock MRI, or booklet). Details of the comparison groups are outlined in **Table 4**. Given the restricted availability of the simulator, child life specialists, and the availability of participants, we are unable to fully randomly allocate participants. As such, participants will be randomly assigned to the intervention options available according to their individual availability (using Research Randomizer https://www.randomizer.org/). For example, if a participant is available on a Thursday that virtual reality and booklet are available, they will be randomly allocated to one of these interventions.

This phase will have open recruitment to all children and adolescents interested in participating, such that participants may not be BCCH patients scheduled for an MRI. This recruitment strategy was selected due to the resource constraints associated with limiting the evaluation group to MRI patients only.

Table 4. Details of the comparison groups.

	VR Simulation	**MRI Preparation Booklet**	**Mock MRI**
Facilitator	Research Assistant	Research Assistant	Child Life Specialist
Location	BCCH	BCCH	Simulation Room
Content	Refer to The Virtual Reality Simulation	Refer to MRI Preparation Book	Individualized intervention in physical simulator.

The different interventions will be held in separate private rooms located in BCCH, such that the VR and booklet groups will not have prior exposure to the imaging centre or the simulation room in advance of their assessment. This is to simulate our intended delivery in hospital, medical office, or clinic settings but minimize alternative explanations associated with testing in the simulation room where assessments will take place (previously described in **Table 3**).

Data will be collected throughout the implementation process (**Figure 3**). The predictive variables (demographics and relevant history, and delivery type) will be captured at the start of the session. The primary outcome variable is likelihood of success (pass/fail) of the MRI simulation, and will be measured at the end of the assessment. Anxiety will also be measured at three time points. Usability testing will be conducted throughout to capture possible quality improvements and amendments to each of the program delivery modes.

Inclusion/Exclusion Criteria

Participants must be between the ages of 4-to-13 years to be included in the evaluation.

The following exclusion criteria, which have been noted in previous studies conducted using virtual reality programs, will be adopted for this project:

- mental disability (content not appropriate)
- significant visual and auditory impairment (this program focuses on auditory and visual cues)
- inability to speak or understand English (content and study staff are English speaking)
- history of seizures or epilepsy (triggered by virtual reality)
- facial or head wounds (cannot wear the virtual reality headset)

Implementation Plan

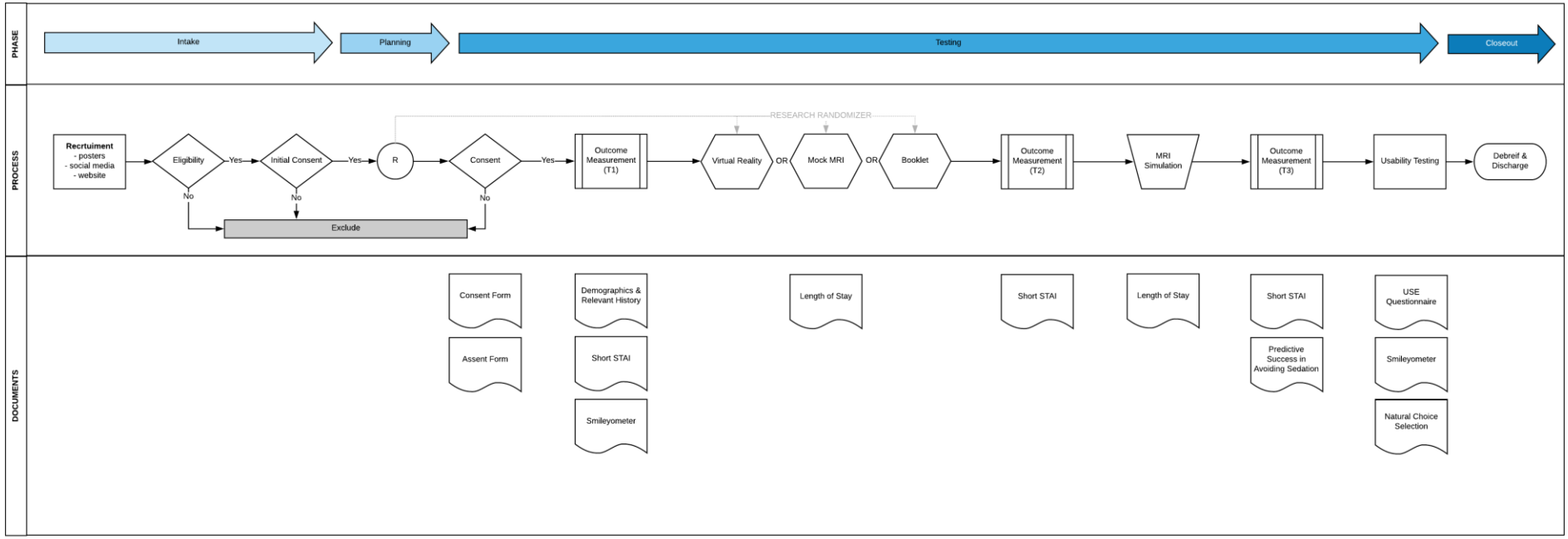

Figure 3. Implementation process.

The testing phase of the implementation process, depicted in Figure 3 will be completed over two hours, and will involve the following steps:

1) Participants and parents/guardians are greeted by staff and enter the intervention room.
2) Staff will obtain written consent from parents and verbal assent from children (5 minutes).
3) Participants will complete the Venham Picture Test (VPT) with staff (pre-test). In parallel, parents will complete the Short STAI on the iPad. (5 minutes)
4) Staff will reveal the allocated delivery mode (VR, mock MRI, or booklet) to the participant and explain the procedure.
5) Staff will ask participants to indicate on the Smileyometer how good they think the intervention is going to be.[30,31] This will give a measure of expectation that can indicate whether or not the participant is subsequently let down by the activity or pleasantly surprised.
6) Staff will measure the participant's interpupillary distance using sliding calipers.
7) Participants will be given 45 active minutes to engage with the intervention. Groups include:

   Group 1 (VR): The VR group will receive a virtual reality simulation designed during Phase 1 of this study.

   Group 2 (mock MRI): The mock MRI will be provided by the CLS, according to the current care plan which consists of exposing children to the mock MRI, medical devices, and procedures. The mock MRI is located within the BCCH medical imaging facility.

   Group 3 (booklet): The standard MRI preparation booklet group will provide access to a series of printed photos and text showing the MRI experience step-by-step to help prepare for the MRI.
8) Participants will be asked to indicate on the Smileyometer how good they actually thought the activity was overall (1 minute).
9) Participants will be informed that they will now be completing a simulation test with the MRI scanner. Participants will be reminded of their free and informed ongoing consent.
10) The participant will be transferred to the simulation room, located in the medical imaging center at BCCH. Upon entering the simulation room, participants will verbally complete the VPT with staff (during test). In parallel, parents will complete the Short STAI on the iPad. (5 minutes)
11) Participants will be guided through a mock MRI and be assessed using MoTrack®, an objective head motion tracking system.[32] The simulation will be completed over 20 minutes and will involve progression through the "MRI procedure", remaining in the bore for 8 minutes. All participants will receive the same type of simulated scan. We will not be simulating any invasive procedures that can sometimes occur during the MRI (i.e. an IV or intravenous contrast liquid). Please note that this assessment involves a mock procedure using the simulator, not a real MRI**.**
12) Immediately following the simulation, participants will verbally complete the VPT with staff (post-test). In parallel, parents will complete the Short STAI on the iPad. (10 minutes).

13) Users will be asked to indicate on the *Smileyometer* how they thought the preparation activity was overall in preparing them for the MRI. Parents/guardians will be asked to complete the USE Questionnaire.
14) Staff will ask the user open-ended questions on the preparation materials according to three separate criteria of fun, ease of use, and how good it was for learning about the MRI experience. The final usability assessment will take a total of 10 minutes.
15) After the session is "complete", children will be told that they "happen to have some time left" so they can play with any of the preparation materials offered (VR, Mock MRI, Booklet) for 5-minutes if they want to "because they did so well during the activity." This will give children a natural choice selection and will be used to gauge preferences for the activities.
16) A verbal session debrief will include an opportunity for questions to mitigate any residual feelings of discomfort or anxiety that may arise from the project's activities.

Outcome Measures

The measures used to evaluate the intended outputs and outcomes associated with this project are outlined below (**Table 4)**.

Table 4. Outputs and outcomes associated with the project.

Measure	**Immediate Outputs**	**Intended Outcome**
Primary		
MoTrak®	# of participants "prepared" to be scheduled for an effective MRI	Improve access to MRI preparation for children who: - Live out of town - Would like to practice skills at home - Have mobility issues Improve non-sedation rates for MRI scans.
Venham Pictoral Test & Short STAI	# of participants with reduced anxiety # of parents with reduced anxiety	Improve access to MRI preparation materials. Improve behavioral compliance during medical procedures.
Secondary		
Smileyometer	# of participants who find the delivery mode fun and engaging to use	Improve acceptability of preparation materials. Improve satisfaction.
USE Questionnaire	# of parents who find the preparation materials useful	Improve acceptability of preparation materials. Improve satisfaction.

Natural Choice Selection	# of participants who select the booklet # of participants who select the mock MRI # of participants who select virtual reality # of participants who select none	Identify preference for engaging. Identify frequency of contact and time engaging.
Length of Stay	Minutes spent per segment	Improve hospital efficiency
Guided Survey	# of participants who find the booklet fun, easy to use, and good for learning about the MRI experience # of participants who find the mock MRI fun, easy of use, and good for learning about the MRI experience # of participants who find the virtual reality game fun, easy of use, and good for learning about the MRI experience	Improve utility of MRI preparation materials. Identify frequency of contact and time engaging.
Interpupillary Distance	Average interpupillary distance per age	Improve headset configuration.

Primary Measures

Predictive Success in Avoiding Sedation

The predictive success in avoiding sedation will be measured using Motrak® software assessment. MoTrak® uses a sensor attached to the participant's head to determine the position of the head in space relative to a transmitter located within the simulator. The sensor records angular rotations as well as positional displacements from an initially calibrated position. This information is displayed and logged by the program in real-time, allowing objective observation of head motion in an MRI simulator.[32] The fail threshold is set at 3mm of movement in any of the positional displacements (x,y,z), which is in accordance with imaging protocols at the Hospital.

Child Anxiety: Venham Picture Test – 5 minutes

Anxiety assessment with children will be completed in pictorial form to better adapt to the cognitive and communicative abilities and styles of younger children. The Venham Picture Test has been well-validated in children for assessing procedural anxiety[33,34], and comprises eight cards which two figures on each card, one anxious character and one non-anxious character. The children will be asked to point at the figure they feel most like at that moment. All cards will be shown in their number order. If the child points at the anxious figure, a score of one is recorded and if the child points at the non-anxious character, they will be given a score of zero. Children will complete the at three timepoints (before, during, after the mock MRI).

Secondary Measures

Parental Anxiety: Short State-Trait Anxiety Inventory (Short STAI) – 5 minutes

Anxiety assessment with parents/guardians and children at baseline, after completing the intervention, and before the mock MRI. The Short STAI is a 6-item, adapted version of the well-validated Spielberger State-Trait Anxiety Inventory Scale.[35] It distinguishes between general proneness to anxious behavior rooted in the personality and anxiety connected to a current state, and has been validated for use in children.[35]

Demographics and Relevant History

Demographic and possible confounding information (age, sex, prior experience with medical imaging, experience with virtual reality, type of mobile phone) will be obtained through a data collection form. Data will be de-identified using a participant identification number.

Length of Stay (LoS)

For the purposes of this evaluation, we will define total LoS as the duration, in minutes, from starting the *preparation* segment to completion of the simulated *assessment*. Inter-segment times will also be recorded. Preparation time will be capped at 45 minutes. Assessment time will be capped at 20 minutes. Start of preparation will be noted as time when study staff finish describing the intervention and indicate it is time to begin the active preparation. Time will stop when the participant is "discharged" from the MRI simulation, before the natural choice selection exercise and debriefing process begins. Time spent transitioning between activities or breaks required for reasons unrelated to the evaluation will not be counted towards overall LoS.

Interpupillary Distance

Interpupillary Distance will assume normal conditions and be measured objectively before preparation using Pryor's (1969) method[36] to ensure appropriate set up of the virtual reality device.

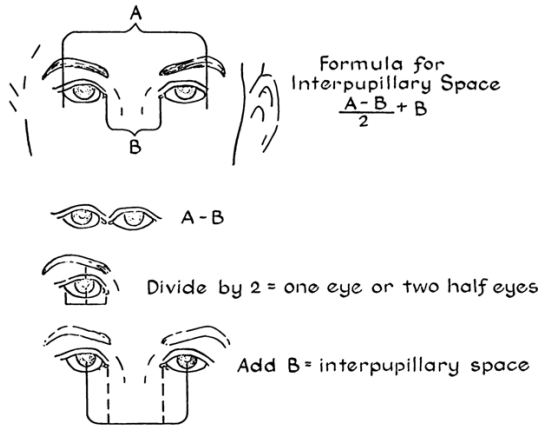

FIG. 1. Formula for interpupillary distance.

Usability Testing

The Smileyometer – 1 minute

The Smileyometer[30,31] is an instrument used for measuring the opinions of technology in children, and has been validated in multiple studies assessing educational materials and software. The Smileyometer is based on the Visual Analogue Scale,[37] consisting of a 5-point Likert scale that uses pictorial representations. Participants are asked to point to the face they relate to.

Guided Survey – 10 minutes

The RA will ask the participant several open-ended questions on the preparation materials according to three separate criteria of fun, ease of use, and how good it was for learning about the MRI experience.

USE Questionnaire – 10 minutes

The USE Questionnaire[23] will be administered to the parents/guardians after the mock MRI only. This will allow participants to compare the VR application to the "effective MRI" experience. The USE Questionnaire is a 7-point Likert rating scale that has been well-validated to assess a program's usefulness, ease-of-use, ease of learning, and satisfaction.

Analysis and Interpretation

A priori power analysis was calculated using G-Power.[38] A total sample size (N) of 93 was calculated to be needed across the 3 groups (31 per group), with a significance level of 95% (a=0.05) and a power of 90% (B=0.10), allowing for a 10% drop out rate. An effect size of 0.2 was selected to reflect the research suggesting that CLS preparation can reduce sedation rates by 20%.

Descriptive analysis will be conducted on the demographics and relevant history data.

Differences in predictive success of the MRI simulation ranking scores (pass or fail) will be examined using a Repeated Measures ANOVA, within-between interaction for three timepoint measurements (before, during, after) of anxiety and delivery type (VR, mock MRI, booklet). In the case of an off-normal distribution, non-parametric tests may be used. Multivariate analysis will test for possible confounding effects (demographics and relevant history).

Survey data (USE questionnaire, Smileyometer) will be analyzed using means and standard deviations of all respondents for each category of the questionnaires. The proportions of the participants reporting high, medium, or low levels will also be calculated.

Study staff will document responses to the guided survey and read the recorded answers back to participants to verify accuracy and elicit possible further reflection. All of the qualitative data will be uploaded to NVivo by study staff. When complete, study staff will code the information to identify major themes, gaps, barriers within the existing approach and the team will devise recommendations for improving the preparation programs. The phases of this process include:

- Familiarizing yourself with the data

- Generating initial codes
- Searching for themes
- Reviewing themes
- Defining and naming the themes
- Triangulation with other findings and producing a report

4.5 Phase 3: Economic Evaluation and Impact Modelling

Objective 3: **Evaluate costs and benefits of the VR solution and status quo; and conduct economic modelling on the prospective impact of operational integration.**

The final phase of this project seeks to answer the following questions:

- What are the current costs of Sedated and Non-Sedated MRI procedures at BC Children's Hospital? (including hospital/health systems costs and average economic burden on patients and families).
- What is the total cost avoidance and opportunity-cost savings in converting a sedated case to a non-sedated case?
- What is the cost-effectiveness of current interventional strategies?
- What is the potential incremental cost-effectiveness ratio of the VR simulation compared to the status quo model (given known limitations)?
- What are the relative impacts to patient/families, hospital, and the health system at large of the various interventions?

The economic modelling will be conducted in a series of stages: (1) cost analysis, (2) outcomes (benefits) analysis, and (3) multi-level modelling of cost-effectiveness (from patient/family, hospital, health systems perspectives).

Stage 1: Cost Analysis

Costs will be analyzed from the perspective of the program implementer (hospital) and estimated for patients/families, and will be reported in Canadian dollars.

For hospital costs, we will analyze administrative/operational costs and clinical volume to present an average case cost for the status quo model and intervention groups. Program costs will be categorized into capital and operational costs, and segmented as technology, administrative, operational and resource costs:

- Technology costs will include hardware devices, technology-related consumables, and technical support. Capital costs for the media development will be measured for the purposes of a parallel return on investment (ROI) analysis, but will be excluded from operational cost-effectiveness analysis (CEA), with the assumption that in many scenarios existing media may be available for use. Multiple CEA models will be produced at varying media costs thresholds, simulating custom content development (using actual incurred/in-kind costs) as well as estimated costs for 'off-the-shelf' media procurement (based on current state market pricing).
- Administrative, Operational and Resources costs will include program management, infrastructure, human resources (e.g. child life specialists, physicians, technologists), medications, associated resources, and consumable supplies.

When presenting the description of the program costs, we will break the components into fixed and variable costs. Fixed costs are defined as not varying, or varying minimally, with the volume of users and variable costs will be tied to the number of users. Fixed costs may include technology, administrative support, staff, and promotional costs. Variable costs may include consumables and medication.

Time-Driven Activity Based Costing (TDABC)

For the analysis of human resources costs, the TDABC methodology will be used to assign costs based on relative resource utilization. TDABC combines business process mapping with detailed assessment of time intervals and resource involvement. The unit cost for each resource will be derived from our review of hospital financial, operational, and clinical volume data (defined as per minute resource costs). Unit costs (per minute estimates) will be multiplied by the relevant time estimate of the activity (or component of), segmented by task and resource.

- The **per minute unit costs** of supplying the capacity will be derived by dividing the total annual costs of individual resources by the minimum annual hours of service. This information will be derived from our review of hospital financial, operational, and clinical volume data.
- **Time estimates** for relevant tasks associated with the programs will be derived from our LoS data and process mapping information gathered in Phase 2

To estimate patient and family costs, multiple scenarios will be defined based on scheduling and administrative data available the Medical Imaging and Child Life Department. No personally identifiable information will be used in any modelling of patient and family costs. Through an analysis of administrative data, we will determine average length of stay for current MRI patients (simulation and actual imaging). Patient/Family costs will be estimated to include opportunity cost (of time spent), travel and accommodation (where applicable – e.g. when simulation and actual imaging are on different dates).

Stage 2: Outcomes (Effects) Analysis

Outcomes will be reported at both the hospital and patient/family perspective, based on the data gathered in Phase 2 (**Table 4**); this includes the predictive non-sedation rates, length of hospital stay, and reductions in anxiety from the patient and family perspectives.

Stage 3: Multi-Level Cost-Effectiveness Modelling

Cost-Effectiveness will be modelled across the various scenarios identified and from multiple perspectives (i.e. hospital, patient/family). To support decision-making, we will determine the **incremental cost-effectiveness ratio** (**ICER**) of the intervention versus the control. ICER is a statistic used to summarise the cost-effectiveness, and is defined by the difference in cost between two possible interventions, divided by the difference in their effect; this represents the average incremental cost associated with 1 additional unit of the measure of effect. For our study, we will measure ICERS for multiple outcome variables that are measured in Phase 2.

Uncertainty Analysis

We expect the number of users, the average amount of consumables and equipment used, and the amount spent on promotional costs to fluctuate. Therefore, we will conduct a probabilistic uncertainty analysis around these program variables to determine sensitivity and what the expected range of cost-effectiveness might be. These values and distribution for the uncertainty analysis will be selected based on one-year data.

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