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REGISTERED REPORT STAGE 1: STUDY DESIGN

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Virtual reality mobility for burn patients (VR-MOBILE): A within-subject-controlled trial protocol

Sylvie Le May[1,2,3] | Christine Genest[2,3] | Maxime Francoeur[1] | Nicole Hung[1,4] | Estelle Guingo[5] | Christelle Khadra[2] | Melanie Noel[6] | Julie Paquette[1] | Andrée-Anne Roy[1]

[1]CHU Sainte-Justine Hospital's Research Centre, Montréal, Québec, Canada

[2]Faculty of Nursing, Université de Montréal, Montréal, Québec, Canada

[3]Centre de recherche de l'Institut Universitaire en Santé Mentale de Montréal (CRIUSMM), Montréal, Québec, Canada

[4]Faculty of Medicine, Université de Montréal, Montréal, Québec, Canada

[5]Department of Creation and NEW Media, Université du Québec en Abitibi-Témiscamingue (UQAT), Rouyn-Noranda, Québec, Canada

[6]Department of Psychology, University of Calgary, Calgary, Alberta, Canada

Correspondence
Sylvie Le May, Sainte-Justine Hospital's, Research Centre, 3175 Cote-Ste-Catherine, TransMedTech Institute, Office 1.7.20, Montreal, Quebec H3T 1C5, Canada.
Email: sylvie.lemay@umontreal.ca

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Abstract

In the acute phase, burn patients undergo several painful procedures. Pediatric burn care procedures conducted in hydrotherapy have been known to generate severe pain intensity and moderate to high levels of anxiety. Hydrotherapy treatments are done with the use of opioids and benzodiazepines for pain and anxiety. Unfortunately, nonpharmacological methods are rarely combined with pharmacological treatments despite evidence showing that distraction can serve as an effective method for pain management and can potentially decrease analgesic requirements in other painful medical procedures. Virtual reality (VR) is a method that uses distraction to interact within a virtual environment. The use of VR is promising for pain reduction in varying settings. Considering the lack of optimal pain and anxiety management during burn wound care and the positive effect of an immersive distraction for painful procedures, using VR for burn wound care procedures may show promising results. This is a within-subject randomized controlled trial design in which each participant will serve as his/her own control. A minimum of 20 participants, aged 7 to 17 years old undergoing a burn care session, will receive both standard and experimental treatments during the same session in a randomized order. The experimental treatment will consist of combining VR distraction using the video game Dreamland® to the current standard pharmacological care as per unit protocol. The control group will only receive the unit's standard pharmacological care. The mean difference in both pain intensity scores and in anxiety between the two different sequences will be the primary outcomes of this study. This study evaluates the effect of VR on burn wound care. If results from this study show a positive effect of VR compared to standard care, this protocol may provide guidance on how to implement this type of immersive care as part of the tools available for distraction of painful procedures for acute burn victims.

KEYWORDS
anxiety, burn care, distraction, hydrotherapy, pain, pediatric

1 | INTRODUCTION

Pediatric burn care procedures in hydrotherapy have been known to generate severe pain intensity as well as moderate to high levels of anxiety. In the acute phase, burn patients undergo several painful procedures including wound debridement, passive range-of-motion (ROM) exercises and dressing change treatments. These procedures are important for proper rehabilitation as they prevent contractures, muscle spasms, and limited joint mobility. These possible complications result from the normal healing process following a burn injury and are mainly due to scarring and loss of skin elasticity.[1,2]

Hydrotherapy in burn care is done with the use of opioids and benzodiazepines, since regular analgesics, such as acetaminophen alone, are often inadequate for pain and anxiety management.[3,4] As hydrotherapy treatments cause a great deal of pain compared to standard burn care, high dose of narcotics is required to reach an acceptable level of pain relief. The delicate balance between pain relief and opioid requirements is often at the limit of respiratory depression and the occurrence of side effects such as nausea and vomiting. Unfortunately, nonpharmacological methods are rarely combined with the pharmacological treatments used to relieve pain during hydrotherapy even if they could decrease the necessary dose of analgesics and benzodiazepines.

Virtual Reality (VR) is a method that uses distraction to interact within a virtual environnement.[3] Flexibility and variety of content make of VR a promising tool for pain reduction, able to be adapted to procedures and to different patient.[5–8] Other positive effects including reduction of anxiety for painful procedures have been reported by children and adults.[9–12] Furthermore, recent randomized-controlled trials[9,10] comparing VR and standard distraction in children during painful procedures demonstrated a significant effect on pain and anxiety which enhanced patients', caregivers' and phlebotomist's satisfaction. Also, Gold and Maher[10] concluded that children with higher anxiety sensitivity had better results, adding support for the adoption of this new technology in children's health care. However, VR is also associated with certain side effects such as an increased nausea and the feeling of cybersickness.[13,14]

Only a few authors have studied the effect of VR on procedural pain and anxiety management in burn children older than 6 years old. Indeed, a review of the literature has yielded only three studies who used VR with burn children.[1,3,15] A study compared the efficacy of VR with standard pharmacological care in an RCT on 54 children (6–19 years) suffering from burn-related injuries with TBSA (total body surface area) varying from 1% to >50%.[1] Results showed better pain control and maximum ROM in children in the VR group.[1] Another study combined participants from three studies (to increase power) to compare the use of VR with standard pharmacological care with children undergoing physical therapy following a major burn.[15] Results on 110 children also showed that VR significantly decreased pain and unpleasantness related to pain in children with burns.[15]

Furthermore, virtual reality has shown positive effects with burn children who underwent hydrotherapy sessions and dressing changes.[16–18] However, very few studies have looked at the effect of VR on the management of pain, anxiety, and recall of both in children undergoing painful burn wound care. Distractions are an interesting nonpharmacological method that can be used, and we believe that a VR distraction as an adjunct to current burn care (standard pharmacological treatment) could be easily adopted by hydrotherapy staff as part of their care as it is an easy to use and low-cost intervention. Other successful VR studies have shown a high satisfaction level among healthcare workers. Their satisfaction level is important for the feasibility aspect of the study as the uptake of the intervention, and its acceptability may influence the possibility of such interventions being implemented at a larger scale in a hospital setting.[19] Also, we believe that it could help make the overall recovery process less painful and less stressful for burn children.

Evidence shows that short-term procedural pain and anxiety can leave long lasting effects on children[20] even after the end of the procedure which is why it is also important to pay attention to the way they remember these experiences.[21,22] Children negatively recalling past pain experiences (i.e., they recall more pain than an earlier pain report) will most likely experience more pain in future experiences, could develop chronic pain problems,[21,22] fears and avoidance of medical care.[23] These negatively based memories seem to be developed prior to painful procedures by anxious and distressed children experiencing higher pain amount.[21,22,24,25] Additionally, one study of youth undergoing vaccine injections showed that interventions to reduce pain and distress (distraction, topical anesthetic) buffered against the development of negatively biased recalls.[26] Therefore, we will also examine the effect of VR distraction on children's later recall of pain and anxiety.

Finally, considering the lack of optimal pain and anxiety management during burn wound care and the positive effect of an immersive distraction method such as VR for painful and anxiety inducing procedures, using VR for burn wound care procedures may show promising results.

2 | AIM OF THE STUDY

The aim of this within-subject randomized clinical trial is to examine the efficacy of an immersive distraction (virtual reality) compared to the standard treatment for pain and anxiety management in children requiring burn wound care (hydrotherapy) sessions.

2.1 | Hypothesis

The use of VR as an adjunct intervention to current burn care (standard pharmacological treatment) will provide better pain and anxiety management than standard pharmacological treatment alone.

2.2 | Objectives

1. To determine if VR distraction combined with analgesics is more effective than standard treatment (analgesics alone) to manage procedural pain of children with burn injuries during hydrotherapy sessions.
2. To compare if VR distraction combined with analgesics is more effective than standard pharmacological treatment to manage procedural anxiety of children with burn injuries during hydrotherapy sessions.
3. To compare if, in children with burn injuries, VR distraction combined with the standard pharmacological treatment sequence generate less recall of procedural pain and anxiety than standard pharmacological treatment alone sequence.
4. To compare the occurrence of side effects between VR distraction combined with the standard pharmacological treatment sequence and standard pharmacological treatment alone sequence.
5. To compare if, in children with burn injuries, VR distraction combined with the standard pharmacological treatment sequence requires less rescue medication than standard pharmacological treatment alone sequence.
6. To compare healthcare professionals' satisfaction levels between VR distraction combined with pharmacological treatment sequence and standard pharmacological treatment alone sequence.
7. To compare children's satisfaction levels between VR distraction combined with standard pharmacological treatment sequence and standard pharmacological treatment alone sequence.

3 | MATERIALS AND METHODS

3.1 | Design

This is a within-subject randomized clinical trial design with randomized sequences. Given the difficulty of ensuring any blinding conditions with the nature of the experimentation, and in order to limit the interpersonal variability between participants, each child will serve as their own control, hence receiving both standard (control) and experimental treatments (VR) during the same treatment session through a randomized order.

3.2 | Sample and setting

Recruitment will be done through convenience sampling upon admission to the surgical-trauma burn unit at CHU Ste-Justine, Montreal (Qc), Canada. Originally, this study also included a follow-up with those same patients at the rehabilitation clinic for physiotherapy. Unfortunately, due to the COVID sanitary crisis, recruiting personnel availability and the difficulty of movement between units and to clinics, recruitment will be limited to the burn unit. Using a within-subject design allows the possibility of recruiting a minimum of 20 participants considered as a total of 40 patients since they will act as their own control.

3.3 | Patient population

3.3.1 | Inclusion criteria

Children (and their parents) will be invited to participate in the study if they meet the following Inclusion criteria: (1) between the ages of 7–17 years old (no child under 7 years old is permitted to use the VR gear); (2) suffering from a burn injury requiring hydrotherapy, and (3) presence of a consenting parent who can understand, read and write either in French or English.

3.3.2 | Exclusion criteria

Children will be excluded from the study if they meet one of the following criteria: (1) suffer from epilepsy considering the nature of the intervention, (2) have burn injuries on the face preventing the use of the Samsung Gear® VR Helmet, and (3) cannot be in a sitting or semi-upright sitting position (semi-Fowler's position) during the procedure as the virtual reality game requires an angle of at least 30 degrees for head-tracking.

3.4 | Ethical considerations

This trial was approved on the 5 January 2021 by the Research and Ethics Board of Ste-Justine Hospital in Montréal, Canada (FWA00021692). It is currently registered on Clinical Trials (clinicaltrials.gov) under the number NCT04538573.

The parents of children admitted to the burn unit who are eligible for this study will be approached for written consent to participate in this study that also includes consent for videotaping. The consent form will be presented by a research nurse to the legal guardian in order to explain the usage of the technology, the expected benefits and side effects, and any other necessary information. Pictures and or videos may be taken during VR sessions, but parents have the option to accept or refuse within the consent form. A consent form will be required for healthcare workers caring for patients during sessions as they will be solicited to complete a questionnaire on satisfaction and pictures might be taken of them during the length of the project. These photos and videos could be used in publications and presentations related to the project as support to the results and to facilitate any explanation of the process.

Every participant will be assigned a unique ID for confidentiality purposes that are used on all data collection forms. Any information log linking study codes and patients' personal information (name and chart number) will only be available to the

research nurse, the principal investigator (SLM), and the medical co-principal investigator (AAR). Patient identifying information will be kept separate from the case reports forms (CRF). Any information linking the patient identifiers to the study ID will be kept securely and locked away for 7 years after the end of this trial at Ste. Justine's Hospital.

3.5 | Interventions and comparisons

3.5.1 | Control treatment

Standard pharmacological care as per the unit's protocol will serve as the control for half of the duration of every treatment session. It consists of different analgesic and sedative medication used in combination in order to help patients go through the procedure. The unit's protocol includes drugs such as Morphine, Hydromorphone, Fentanyl, Clonidine, Ketamine, Midazolam, and Acetaminophen.

3.5.2 | Experimental treatment

VR distraction combined with the standard pharmacological care. In this study, "Dreamland®," a videogame developed by our independent collaborators, uses VR technology showing interactive and personalized content that is tailored to children. This videogame was developed in a way to minimize the feeling of cybersickness and to maximize immersion by guiding the movement of participants on a set path through space. The game was approved by a team of healthcare professionals in pediatric care and is in an arcade style where participants are floating from island to island and throwing balls at giant balloons in order to gain points. In "Dreamland®," the player's vision is controlled by head movement and balls are thrown by pressing buttons on the controllers in the child's hands. In the event that the child is burned on both arms, the throwing aspect will be performed by the research nurse or child life specialist while the child would be responsible for controlling direction. The game does not have set objective making it easier for anyone to play no matter talent or experience with videogames.

3.6 | Study proceedings

The duration of a hydrotherapy session lasts about 20–30 min and will be divided into two sequences of equal durations (10–15 min) where the participant will receive the same care by the same healthcare professional. For one sequence, only the standard treatment will be administered and for the other sequence, children will receive the standard treatment and VR, in a randomized order. Because of the necessary study design, only the first sequence will be used for rescue medication to decrease carryover.

3.7 | Study time-points

Measures of pain with the Verbal Numerical Rating Scale (VNRS 0–10) and anxiety with the Child Fear Scale (CFS, 0–4) will be taken before the treatment session at (T0), after the first sequence of the session (T1) and after the second sequence of the session (T2) followed by a measure of healthcare professionals' level of satisfaction via a questionnaire developed and pretested by the team. Recall of pain and anxiety will be assessed about a week after the procedure (T3). Data will also be collected on the occurrence of side effects. Clinical monitoring will be performed by a research nurse independent from the research team.

4 | MEASURES AND OUTCOMES

4.1 | Sociodemographic and clinical questionnaire

Demographic and clinical characteristics will be assessed with parent reports and hospital chart review filled out by the research nurse using the CRF and will also include age, sex, gender, ethnicity, cause of burns, TBSA, location of the burn, number of wounds, dept of each burn, and the number of hydrotherapy sessions already undergone (if necessary).

4.2 | Primary and secondary outcomes measures

4.2.1 | Primary outcomes

The primary outcomes of this study will include the mean difference in both pain intensity scores and anxiety intensity between the two different sequences.

4.2.2 | Measures of primary outcomes

The assessment of pain intensity will be done using the Verbal Numerical Rating Scale (VNRS). It is an 11-item scale for pain intensity ranging from 0 to 10; 0 = no pain to 10 = worst pain ever felt.[27] This scale is considered valid (Convergent validity with Faces Pain Scale-R: $r = 0.75–0.93$) and reliable (test–retest using Bland–Altman agreement: −0.9 to 1.2, 95%CI) for self-reported pain intensity in children and adolescents.[28–31] The assessment of anxiety will be done using the Child Fear Scale (CFS)[32] immediately after the first sequence (T1) and the second sequence (T2) of the procedure. The CFS is a self-reported measure of anxiety adapted from the adult Faces Anxiety Scale[33] that can be used to assess children during painful procedures. This scale from 0 to 4 consists of five images of drawn faces ranging from a neutral expression associated with a 0 rating through a very fearful or anxious expression associated with a rating of 4. When asked, the child will then indicate which face

on the scale best represent how they felt at specific timepoints of the study. This scale is considered valid for this experiment (test–retest reliability: rs = 0.76) and also valid (convergent validity with the Children Anxiety and Pain Scale [CAPS]: rs = 0.73).[34] The CFS scale was chosen due to its psychometric qualities and because it allows self-measure of anxiety/fear with only one item. Moreover, "although fear tends to decrease with age in general, medical fears may be an exception,"[35(p.443)] "age-related differences in fear ratings have not been found."[36(p.739)] Further, the CFS has been used for fear assessment in previous venipuncture experiment[37] on children aged 8–18 years and for fear and anxiety assessment during vaccination children 11–13.[38]

4.2.3 | Secondary outcomes

The different secondary outcomes will be (A) mean difference in the different components of pain (cognitive, affective, and sensory) as well as immersion and engagement in the VR world between groups; (B) children's satisfaction levels; (C) healthcare professionals' satisfaction level; (D) occurrence of side effects during and immediately after the procedure; (E) mean differences in children's recall of pain within one week after the procedure (T3); and (F) mean differences in children's recall of anxiety within one week after the procedure (T3).

4.2.4 | Measures of secondary outcomes

Secondary outcomes measures will be (A) The Graphic Rating Scale (GRS)[1,39] will be used to measure the different components of pain (cognitive, affective, and sensory) as well as immersion and engagement in the VR world. This is a 7-item scale that is tailored for children during VR interventions that is considered as valid (convergent validity was $r = 0.84$ and test–retest reliability was 0.91[39]); (B) children's satisfaction levels will be measured by asking questions recommended by PedIMMPACT such as: "Considering pain relief, side effects, physical recovery, and emotional recovery, how satisfied were you with the treatments you received for pain?"[40] with a numerical scale ranging from 0 to 10. (C) A 7-item tailored questionnaire will be used in order to assess healthcare professional's satisfaction level with the intervention performed using a four-answer format ranging from Strongly agree to Strongly disagree. (D) Any side effects will be documented for the entire study period and measured using the Graphic Rating Scale (GRS); (E) the VNRS scale used for the assessment of pain as written in the primary outcomes will also be used in order to measure the level of recall anxiety one week after the intervention with questions framed differently to account for recall. In the event that the next hydrotherapy session is scheduled before the one-week mark, we will make sure to measure recall before the next session. (F) The CFS scale used for the assessment of anxiety as written in the primary outcomes will also be used in order to measure the level of recall anxiety one week after the intervention with questions framed differently to account for recall. Parental satisfaction will not be measured as parents are not allowed in the hydrotherapy room.

4.2.5 | Co-interventions

As per the CRF, any additional distraction that may spontaneously be used during sessions such as blowing bubbles will be documented. Furthermore, it is expected that child life specialist be present to help assisting nurses to install and direct children with their expertise.

4.3 | Sample size

Recruiting 20 patients being their own control will provide a total of 40 patients, which is necessary to achieve 80% power to reject the null hypothesis of equal means when the population mean difference for pain of 2.0 with a standard deviation of 1.0, a mean difference for anxiety of 1.0 with a standard deviation of 1.0 and a significance level (alpha) of 0.05 for both components. This sample size considers an attrition rate of 10%.

4.4 | Statistical analysis

Comparisons will be conducted within and between subjects for the dependent variables for repeated measures. The mean difference in pain scores of patients at each time period will be compared using a paired t-test or Wilcoxon sign-rank test. Since the use of rescue medication is a potential indication of a treatment failure, the primary analysis will be supplemented by an analysis comparing the proportion of patients receiving rescue medication anytime during the procedure. Interpretation of the primary analyses will be made with reference to the data regarding rescue medication use. Data collected on dichotomous variables will be analyzed using a chi-square test and post hoc analyses if the results are statistically significant. Statistics will be performed by an independent biostatistician from the URCA (Applied Clinical Research Unit of CHU Sainte-Justine).

5 | DISCUSSION

This trial is designed as a randomized, single centered, within-subject controlled study aiming to test the hypothesis that immersive distraction (virtual reality) may improve pain and anxiety management in children compared to the standard care during burn wound care.

Results from different studies have shown that an immersive distraction such as VR is effective compared to standard burn care for range of motion[1] and pain.[15] However, to the best of our knowledge, no other study has investigated the effect of VR during hydrotherapy burn care sessions on pain and anxiety recall. As previously discussed,

buffering against the conception of negatively biased recalls can positively impact a child's well-being. We strongly believe that immersive VR is an innovative intervention that could be offered to most of the children undergoing painful medical procedures. For children eligible to use VR, we expect that the intervention described in this protocol will provide a more immersive distraction and divert their attention from the source of pain and anxiety during a painful procedure. For healthcare workers, we expect to see an increased collaboration from calmer children from reduced pain and anxiety and simplification of their work during hydrotherapy. It is a low-cost, easy-to-use intervention that could be setup in a few minutes but do requires support from a child life specialist to install it on the child's head and provide guidance and information before the initiation of the game.[41]

In summary, if results from this study show a positive effect of VR compared to standard care, this protocol may provide guidance on how to implement this type of distraction among the interventions or tools available to distract acute burn victims during burn wound care.

5.1 | Challenges and limitations

Recruitment of the necessary sample size of patients may be difficult to estimate as cases of burn injuries happen randomly. Further, the game used during this study was designed by expert collaborators to our research team to be engaging for our target audience, to be easy to use within the parameters necessary to the completion of the study, and to minimize cybersickness. As a result, conclusions from this study may be difficult to extrapolate outside of our own controlled setting and may need the same game or another one designed with the same parameters in mind.

6 | CONCLUSION

This project will provide evidence-based knowledge on a nonpharmacological method for pain and anxiety management for burn patients through innovative interventions. Effective management of pain and anxiety during repeated painful procedures early in life could buffer against the development of fears and avoidance of medical care and the development of persistent pain problems into adulthood. While our study provides an alternative method to managing pain and anxiety, it is also tailored to the target audience and the hospital setting (hydrotherapy) demanding specific parameters such as a waterproof case which the Samsung Gear® VR system offers.

AUTHOR CONTRIBUTIONS

SLM and CK contributed to the conception and design of the trial and to the drafting and critical revision of the article. CG, MF, JP, EG, AAR, and NH participated in the drafting and revision of the final version of the protocol. All authors read and approved the final manuscript.

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CONFLICTS OF INTEREST

The authors report no conflicts of interest in this work.

ORCID

Maxime Francoeur https://orcid.org/0000-0002-8652-4707
Nicole Hung https://orcid.org/0000-0003-1016-559X

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