HITLAB

mirawell

Advancing Pediatric Pain and Anxiety Management Through Biofeedback-Enabled Virtual Reality by Mirawell Health

A Summary of Evidence Paper

This evidence synthesis report by HITLAB evaluates Mirawell Health's clinical validation, user experience, economic value, and market potential as a scalable, non-pharmacologic solution for pediatric pain and anxiety management.

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CONTENTS

Executive Summary	3
Background & Clinical Problem	4
Gap & Needs Assessment	9
Platform Overview	13
HITLAB Heuristic Evaluation	22
Clinical Outcome Evidence	26
Extended Validation	35
Economic Value Analysis	47
Mirawell Health: Evidence, Deployment and Scalability	52
User Feedback	55
Conclusion	57
References	58

Executive Summary

The Growing Burden of Pediatric Pain and Anxiety

Pediatric pain and anxiety remain substantial clinical challenges across oncology, surgery, chronic disease management, and supportive care. Children may experience repeated painful procedures, prolonged treatment journeys, and treatment-related psychological stress, while existing approaches often rely on pharmacologic interventions and subjective symptom reporting. Scalable, engaging, non-pharmacologic solutions that support self-regulation and integrate efficiently into clinical workflows remain limited.

Mirawell Health addresses this gap through an immersive pediatric platform combining guided breathing, physiological biofeedback, and interactive virtual reality to support pain, anxiety, and stress management.

Clinical Evidence and Validation

The evidence reviewed provides a credible foundation for Mirawell Health's continued clinical development. Feasibility and pilot randomized studies demonstrated strong recruitment, retention, adherence, and patient and caregiver acceptability, with no serious adverse events reported. The short-term improvements in pain intensity, pain unpleasantness, and anxiety, while protocol-development research supported repeated physiological self-regulation training. Early evidence indicates strong patient engagement, favorable usability, and growing clinical interest in biofeedback-enabled approaches that promote self-regulation and skill development rather than passive distraction alone.

Strategic Opportunity and Future Potential

Mirawell Health demonstrated several attributes that support future clinical deployment and scalability. HITLAB's heuristic evaluation identified a highly engaging breathing-guided experience, intuitive pediatric-focused interactions, immersive environments, and strong potential for reducing treatment-related stress through non-pharmacologic supportive care. The platform's integration of guided breathing, biofeedback, gamification, and immersive VR creates a differentiated user experience that aligns well with the needs of pediatric patients, caregivers, and healthcare providers. Mirawell Health may support both immediate symptom relief and the development of longer-term self-regulation skills through repeated use.

The platform also benefits from a scalable technology foundation that supports use across pediatric oncology, perioperative care, procedural anxiety management, and other supportive-care settings.

Mirawell Health is well positioned to address growing demand for non-pharmacologic pediatric pain and anxiety management. Its scalable VR-biofeedback platform supports opportunities across pediatric oncology, surgery, chronic pain, rehabilitation, and supportive care settings, while aligning with healthcare priorities focused on patient experience, opioid reduction, and digital therapeutics.

Mirawell Health is supported by a growing and increasingly diverse body of evidence spanning clinical feasibility studies, pilot randomized trials, protocol-development research, independent usability assessments, and external validation literature. Collectively, these findings demonstrate strong patient engagement, favorable acceptability, promising physiological training outcomes, and meaningful potential for reducing pain, anxiety, and treatment-related distress in pediatric populations. Its unique integration of biofeedback, guided breathing, and immersive virtual reality positions Mirawell Health as a differentiated non-pharmacologic supportive-care solution that aligns with evolving healthcare priorities focused on patient-centered care, opioid reduction, and scalable digital therapeutics. While continued clinical validation remains important, the current evidence provides a strong foundation supporting Mirawell Health's potential for broader adoption across pediatric oncology, perioperative care, procedural support, and future supportive-care applications.

Background & Clinical Problem

The Growing Burden of Pain and the Shift Toward Non-Pharmacological Care

Pain remains one of the most significant unmet needs across cancer care, chronic disease management, and end-of-life care. Worldwide, there were an estimated 19.3 million new cancer cases and 10.0 million cancer deaths in 2020, and the global cancer burden is projected to increase to approximately 29.5 million new cancer cases and 16.5 million deaths by 2040 (Sung et al., 2021; International Agency for Research on Cancer [IARC], 2020; National Cancer Institute [NCI], 2026).

At the same time, healthcare systems are increasingly reducing reliance on opioid-based pain management. Between 2013 and 2017, opioid prescribing declined by approximately 21% among oncologists and 23% among non-oncologists treating Medicare beneficiaries in the United States (Jairam et al., 2021; NCI, 2020).

Chronic pain remains a major public health challenge, affecting 24.3% of U.S. adults in 2023, while 8.5% of adults experienced high-impact chronic pain that frequently limited daily activities or work (Lucas & Sohi, 2024).

These trends underscore the growing need for evidence-based, non-pharmacological interventions that can support pain management, reduce anxiety, improve self-regulation, and complement traditional clinical care.

Epidemiological Evidence

Cancer Burden: The worldwide cancer burden continues to increase, with 19.3 million new cancer cases and 10.0 million cancer deaths reported in 2020 (IARC, 2020).The U.S. National Cancer Institute projects this burden to rise to 29.5 million new cases and 16.5 million deaths globally by 2040, driven primarily by population ageing and growth (NCI, 2026).

Chronic Pain: Chronic pain affects nearly one in four American adults. In 2023, 24.3% of U.S. adults reported chronic pain, with 8.5% experiencing high-impact chronic pain (Lucas & Sohi, 2024).Earlier CDC estimates found that 20.9% of U.S. adults, equivalent to 51.6 million individuals, experienced chronic pain in 2021, while 17.1 million adults experienced high-impact chronic pain (Rikard et al., 2023). Chronic pain prevalence among U.S. adults increased from 20.4% in 2019 to 24.3% in 2023, while high-impact chronic pain increased from 7.4% to 8.5% (Lucas & Sohi, 2024).

Hospice and End-of-Life Care: Hospice utilization continues to expand. In 2021, more than 1.7 million Medicare beneficiaries received hospice services, while Medicare hospice expenditures reached $23.1 billion (CMS, 2023).Collectively, these epidemiological data demonstrate a substantial and growing population requiring effective symptom-management strategies, particularly approaches that can complement medication-based care and improve patient quality of life.

20 million
global cancer cases in 2022.

35 million
projected annual cancer cases by 2050.

53.5 million
cancer survivors living within 5 years of diagnosis globally.

25–33%
of children experience chronic pain globally.

1 in 20
children experiences debilitating chronic pain.

21 million
children require pediatric palliative care annually.

Background & Clinical Problem

Global scenario

Clinical Area	Evidence Statement	Reference	Insights for Mirawell Health
Cancer Burden	Approximately **20 million new cancer cases and 9.7 million cancer deaths** occurred worldwide in 2022.	Bray et al., 2024	Growing cancer incidence increases demand for supportive-care solutions addressing pain, anxiety, and treatment-related distress.
Future Cancer Burden	Annual global cancer cases are projected to reach **35 million by 2050, representing a 77% increase** from 2022 levels.	Bray et al., 2024	Supports development of scalable symptom-management technologies capable of serving larger patient populations.
Cancer Survivorship	Approximately **53.5 million people worldwide were alive within five years of receiving a cancer diagnosis** in 2022.	WHO, 2024	Large survivorship populations require ongoing management of pain, fatigue, emotional distress, and quality of life.
Pediatric Chronic Pain	**Chronic pain** is experienced by approximately **one-quarter to one-third of children worldwide, with approximately 1 in 20 experiencing debilitating pain.**	WHO, 2020	Establishes a substantial global pediatric population that may benefit from non-pharmacologic pain-management approaches.
Impact of Pediatric Chronic Pain	Children with chronic pain experience **higher rates of disability, anxiety, depression, sleep disturbance, and reduced school participation**.	WHO, 2020	Supports evaluation of outcomes beyond pain intensity, including emotional and functional outcomes.

Background & Clinical Problem

Global scenario

Clinical Area	Evidence Statement	Reference	Insights for Mirawell Health
Pediatric Palliative Care Need	Up to **21 million children globally** may require pediatric palliative care annually.	WHO, 2018	Demonstrates a substantial unmet global need for symptom-management support.
Pediatric Palliative-Care Access Gap	WHO reports **major gaps in pediatric palliative-care** availability globally, with many countries lacking specialized services.	WHO, 2018	Highlights opportunities for scalable supportive-care technologies.
Chronic Pain Burden Trends	Global prevalence and disability associated with **chronic pain increased significantly between 1990 and 2019.**	Zhu et al., 2024	Indicates growing long-term demand for chronic-pain interventions globally.
Pediatric Oncology Procedures	Pediatric cancer patients frequently undergo painful and anxiety-**provoking procedures such as venipuncture, lumbar puncture, and bone marrow aspiration.**	Cheng et al., 2022	Directly aligns with Mirawell Health's procedural-pain and anxiety-management focus.

Background & Clinical Problem

The United States

Clinical Area	Evidence Statement	Reference	Insights for Mirawell Health
Adult Chronic Pain	In 2023, **24.3% of U.S. adults experienced chronic pain and 8.5% experienced high-impact chronic pain.**	Lucas & Sohi, 2024	Demonstrates the broader future opportunity for digital pain-management solutions.
Growth in Chronic Pain	Chronic pain prevalence increased from **20.4% in 2019 to 24.3% in 2023; high-impact chronic pain increased from 7.4% to 8.5%.**	Lucas & Sohi, 2024	Indicates worsening burden and increasing demand for scalable interventions.
Pediatric Cancer Incidence	An estimated **14,910 children and adolescents aged 0–19 years** were expected to be diagnosed with cancer in 2024.	National Cancer Institute, 2024	Supports Mirawell Health's pediatric oncology beachhead strategy.
Pediatric Cancer Mortality	Approximately **1,590 children and adolescents** were projected to die from cancer in 2024.	National Cancer Institute, 2024	Highlights the need for supportive and palliative-care solutions.
Childhood Cancer Survivorship	Approximately **495,739 childhood and adolescent cancer survivors** were alive in the U.S. as of January 1, 2020.	National Cancer Institute, 2024	Supports survivorship and long-term supportive-care opportunities.
Childhood Cancer Trends	The incidence of childhood and adolescent cancer was **18.2 per 100,000 population** between 2001 and 2022.	Shiels et al., 2026	Demonstrates a sustained pediatric oncology population requiring supportive interventions.

Background & Clinical Problem

The United States

Clinical Area	Evidence Statement	Reference	Insights for Mirawell Health
Pediatric Pain Economic Burden	Pediatric pain-related conditions generate approximately **$11.8 billion in annual incremental healthcare expenditures.**	Groenewald et al., 2015	Demonstrates the substantial economic burden of pediatric pain.
Adolescent Chronic Pain Cost	Moderate-to-severe adolescent chronic pain generates approximately **$19.5 billion in annual societal costs** in the United States.	Groenewald et al., 2014	Suggests a strong economic rationale for effective interventions.

14,910
pediatric cancer diagnoses annually in the U.S.

495,739
childhood cancer survivors living in the U.S.

$11.8B
annual U.S. healthcare burden from pediatric pain conditions.

$19.5B
annual societal cost of adolescent chronic pain.

Pediatric pain is associated with anxiety, disability, sleep disruption, repeated healthcare utilization, and family burden. Mirawell Health is therefore positioned as a supportive-care pediatric pain management platform.

Gap & Needs Assessment

Cancer-Related Pain Represents a Significant and Persistent Unmet Need

In this randomized trial (Karthic et al., 2023), 128 adolescent–parent dyads were randomized to watch either a behavioral economics-informed recruitment video (using altruism/reciprocity and descriptive social norms) or a standard biological video for a future clinical trial on biofeedback-based virtual reality for postoperative pain. The behavioral economics approach did not increase enrollment intentions (75% vs. 79%, p = 0.744) but significantly reduced perceived risk (p = 0.023). Overall, 77% of participants expressed willingness to enroll, highlighting high baseline interest regardless of recruitment framing.

- Pain is one of the most common and burdensome symptoms experienced by individuals diagnosed with cancer and can arise from the disease itself, cancer treatments, surgical procedures, or long-term treatment-related complications.
- As cancer survival rates continue to improve and the number of cancer survivors increases, the demand for effective, scalable, and patient-centered pain management solutions is expected to grow.

These trends highlight the need for evidence-based, non-pharmacological interventions that can complement traditional treatment approaches, reduce symptom burden, improve patient quality of life, and support long-term survivorship care. There is a persistent challenge of recruitment in pediatric pain research—a gap that calls for patient-centered, engaging, and clinically validated digital solutions that families can readily trust and adopt. Mirawell Health Antima no delivers exactly that: an evidence-based platform that aligns with adolescents' expressed interest in non-pharmacological pain technologies, offering a practical and scalable way to translate research insights into real-world relief.

Behavioral Economic Strategies to Enhance Recruitment Into a Pediatric Randomized Clinical Trial for Postoperative Pain Relief

In this randomized trial (Karthic et al., 2023), 128 adolescent–parent dyads were randomized to watch either a behavioral economics-informed recruitment video (using altruism/reciprocity and descriptive social norms) or a standard biological video for a future clinical trial on biofeedback-based virtual reality for postoperative pain. The behavioral economics approach did not increase enrollment intentions (75% vs. 79%, p = 0.744) but significantly reduced perceived risk (p = 0.023).

Overall, 77% of participants expressed willingness to enroll, highlighting high baseline interest regardless of recruitment framing.

- **No Significant Difference in Enrollment Intentions:** 75% in the behavioral economics group vs. 79% in the control group intended to enroll (p = 0.744); >4,000 patients would be needed to detect a significant difference at the observed rates.
- **Reduced Risk Perception in Behavioral Economics Group:** Median risk score was 2.0 [1.0–2.0] vs. 2.0 [2.0–3.0] in controls (p = 0.023).
- **No Differences in Secondary Outcomes:** Intention to adhere (p = 0.084), acceptability (p = 0.376), efficacy perception (p = 0.914), and treatment burden (p = 0.251) were all statistically comparable.
- **High Overall Enrollment Willingness:** 77% (97/126) of all participants agreed to join the future trial, regardless of video type.
- **Preoperative Recruitment Advantage:** Achieved 77% willingness vs. 43% in prior postoperative recruitment, suggesting timing is a more potent driver than messaging.

Gap & Needs Assessment

Pediatric pain management

Current pediatric pain management relies heavily on opioids, sedatives, and subjective pain assessments despite growing concerns regarding opioid exposure, persistent opioid use, and variability in perioperative care delivery. Many hospitals lack standardized, non-pharmacologic tools that can objectively measure physiologic distress while reducing pain and anxiety during treatment (Harbaugh et al., 2018; Berry et al., 2021).

Current Challenge	Evidence
Annual pediatric surgeries in the U.S.	3.9 million
Children undergoing surgery annually	3.1 million
Continued opioid dependence after surgery	4.8% of opioid-naïve adolescents develop persistent opioid use after surgery
Reliance on subjective pain scales	Limited objective physiologic monitoring during pain management
Variability in pediatric surgical expertise	Half of hospitals perform fewer than 10 pediatric inpatient surgeries annually
Anxiety amplification of pain	Pain and anxiety frequently co-exist during pediatric procedures
Limited scalable supportive care tools	Existing options are labor-intensive or pharmacologic
Inequitable access to care	Minority and uninsured children experience lower surgical access rates

Leveraging VR/AR to Combat Chronic Pain in Youth

In this consensus position paper (Logan et al., INOVATE-Pain Consortium, 2020), 16 interdisciplinary experts from academia, clinical care, industry, and philanthropy convened in January 2020 to establish best practices for developing and evaluating VR/AR interventions for pediatric chronic pain. The consortium identified key challenges—including industry–academic timeline mismatches, regulatory hurdles, proliferation of unvalidated products, and lack of standardized outcome measures—and proposed recommendations across team assembly, technology selection, research design, and dissemination. Recommended outcome domains include pain intensity, pain interference, functioning, fear of pain/movement, pain catastrophizing, affect, satisfaction, and VR-specific metrics (movement, energy expenditure, physiology, immersion/presence).

- **Key challenges identified:** Differing pace and regulatory barriers between industry and academia; proliferation of unvalidated VR products; pediatric adoption barriers (safety, hardware fit, infection control, reimbursement).
- **Recommended outcome domains:** Pain intensity/unpleasantness, pain interference, functioning, fear of pain/movement, pain catastrophizing, affect, satisfaction with treatment, and VR-specific physical movement, energy expenditure, physiology, and immersion/presence.

Mirawell Health addresses critical gaps in pediatric perioperative care by combining real-time physiologic monitoring, biofeedback, and adaptive VR to reduce pain, anxiety, and opioid reliance. Its scalable, non-pharmacologic approach supports improved patient outcomes, workflow efficiency, and broader access to high-quality supportive care across pediatric surgical settings.

Gap & Needs Assessment

Gap Category	Unmet Need / Gap	Verified Evidence	Reference	Mirawell Health Relevance
Pediatric Palliative-Care Gap	Global access to supportive care remains inadequate.	Up to **21 million children** globally may require pediatric palliative care annually.	WHO, 2018	Demonstrates substantial unmet supportive-care needs.
Access Inequity	Most children needing symptom-management care live in under-resourced regions.	More than **98% of children** experiencing serious health-related suffering live in low- and middle-income countries.	WHO, 2018	Long-term opportunity for scalable digital interventions.
Persistent Opioid Use	Opioid exposure following surgery creates long-term dependency risk.	Persistent opioid use occurred in **4.8% of opioid-naïve surgical patients aged 13–21 years compared with 0.1% of nonsurgical controls**.	Harbaugh et al., 2018	Supports interest in opioid-sparing treatment pathways.
Opioid Overprescribing	Pediatric surgery frequently results in excess opioid supply.	Reviews report that as much as **71% of dispensed postoperative opioid tablets remain unused**.	Odegard & Kelley-Quon, 2022	Highlights medication-safety and diversion risks.
Preoperative Anxiety	Anxiety is highly prevalent before surgery.	In a prospective cohort of 500 adolescents, **37.4% reported anxiety before surgery**.	Sutherland et al., 2025	Identifies anxiety reduction as an important clinical objective.
Chronic Postsurgical Pain	A significant portion of children experience long-term pain after surgery.	The pooled prevalence of pediatric chronic postsurgical pain was estimated at **28.2%**.	Rosenbloom et al., 2025	Suggests a need for interventions extending beyond immediate postoperative recovery.

Gap & Needs Assessment

Gap Category	Unmet Need / Gap	Verified Evidence	Reference	Mirawell Health Relevance
Pediatric Pain Expenditure	Pediatric pain creates a substantial healthcare burden.	Pediatric pain-related conditions were associated with approximately **$11.8 billion in annual incremental U.S. healthcare expenditures**.	Groenewald et al., 2015	Supports the economic rationale for better symptom management.
Limited Anxiety-Focused Interventions	Many pediatric surgical pathways lack structured anxiety management.	Meta-analysis found **VR significantly reduced preoperative anxiety in pediatric surgical patients**.	Ahmed et al., 2025	Supports anxiety as a primary treatment target.
Need for Procedure-Specific Pain Relief	Needle-related procedures remain a major source of pain and fear.	Meta-analysis of nine randomized trials found **VR significantly reduced procedural pain, anxiety, and fear.**	Jing et al., 2026	Supports use in oncology and procedural-care environments.
Need for Non-Pharmacologic Approaches	Psychological and behavioral interventions are effective but not consistently available.	Systematic reviews demonstrate **reductions in pain symptoms and disability from psychological pain-management interventions** in pediatric populations.	Fisher et al., 2014	Supports biofeedback and self-regulation approaches as part of multimodal care.

The evidence consistently demonstrates a substantial unmet need in pediatric pain, anxiety, and supportive care, driven by high rates of chronic pain, procedural distress, persistent postoperative pain, and limited access to specialized symptom-management services. Current care pathways remain heavily reliant on opioids and subjective symptom assessment, while many healthcare systems lack scalable, engaging, and non-pharmacologic interventions that can effectively support children during treatment and recovery. External evidence supports virtual reality, behavioral interventions, and self-regulation approaches as promising strategies for reducing pediatric pain, anxiety, and procedural distress, highlighting the rationale for further evaluation of biofeedback-driven platforms such as Mirawell Health within routine clinical care

Platform Overview

Mirawell Health is a closed-loop biofeedback system that combines real-time physiological monitoring with immersive therapeutic technology to help individuals reduce pain and anxiety through natural, science-backed methods.

Built by pediatricians for the pediatric population, Mirawell Health addresses a fundamental gap in how pain and stress-mediated conditions are managed—offering an alternative approach that moves beyond medication alone. The system teaches users to understand and regulate their bodies in real time, providing a pathway to relief that is both immediate and sustainable

Target Population: Pediatric patients ages 6–22, with initial commercial pilots focused on oncology patients—a population with significant unmet needs in pain and anxiety management during in-clinic procedures.

Core Value Proposition

Dimension	Description
Clinical Evidence	A randomized clinical trial in 70 patients demonstrated that Mirawell Health's VR-based biofeedback is safe, well-liked, and produces meaningful reductions in pain and anxiety within minutes—without any serious side effects.
Regulatory Posture	Operates under an FDA-exempt General Wellness framework, enabling rapid deployment without the regulatory burden of a therapeutic device—while maintaining clinical-grade rigor in sensor selection and system design.
Pediatric Focus	Purpose-built for children and adolescents, with a leadership team that includes anesthesiologists, psychologists, and biofeedback researchers from leading pediatric institutions including Nemours Children's Health, Cincinnati Children's Hospital, and Stanford University School of Medicine.
Science-Backed Approach	Biofeedback trains the nervous system to rebalance itself. By improving breathing and heart rate variability (HRV), it reduces pain, stress, and emotional overload. Mirawell Health brings this proven science into a modern, accessible tool.

Platform Overview

Product Components

Component	Description	Key Device Design Features
Wearable Biofeedback Sensor	A chest-worn device that measures breathing, heart rate variability (HRV), and stress signals in real time. The system requires: • Heart Rate (HR): Accurate to within ~5 bpm of ECG reference under resting and low-motion conditions. • Heart Rate Variability (HRV): R-R interval data with sufficient sampling fidelity for time-domain measures (SDNN, RMSSD) and basic frequency-domain analysis. • Respiratory Rate (RR): Derived from chest-wall measurement or ECG-derived respiratory sinus arrhythmia (RSA). The sensor landscape assessment identified Movesense Medical (CE-MDR Class IIa cleared, ECG-based HR/HRV/RR, programmable platform) as the primary candidate, with Sibel Health ANNE One (FDA 510(k) cleared for ages 12+) as the secondary candidate for pediatric deployment.	Fully untethered VR-BF system Real-time physiological integration into gameplay Pediatric-specific design Supports both hospital and home use Tracks: Engagement, Physiological performance, Adherence over time
Personalized Mobile App	Delivers immersive modules and micro-exercises that quickly shift autonomic state and ease pain and anxiety.	
Immersive VR Therapy	Guided virtual experiences that use live biofeedback to help regulate pain, stress, and anxiety in real time.	Eliminates need for clinician-supervised BF sessions

Platform Overview

Product Components

ForeVR System Overview

- ForeVR (Functional Outcome Response to Engaging VR) is a VR-based biofeedback system designed for pediatric perioperative pain and opioid reduction.

- It combines:
  - **Virtual reality immersion (Meta Quest 2 headset)**
  - **Real-time heart rate variability (HRV) biofeedback**
  - **Respiratory rate biofeedback**

- It enables patients to self-train slow breathing and HRV control without requiring a trained clinician.

- The system translates physiological performance into game progress and rewards, reinforcing correct biofeedback behavior.

VR hardware platform

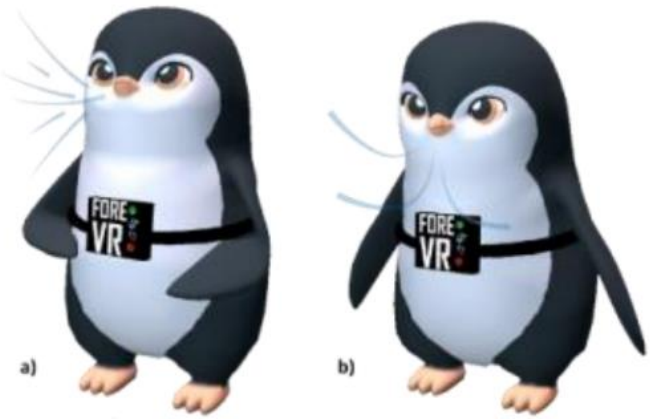
- Uses the Meta Quest 2 VR headset
- Non-invasive, commercially available
- Untethered ("all-in-one" system)
- Registered and managed via ManageXR

ForeVR device

Hardware Components of ForeVR

- Physiological sensing hardware

- ForeVR includes hardware that measures:
  - Heart rate / HRV
  - Captured via an ear clip sensor
  - Respiratory rate
  - Captured via a chest monitor



User Training & Coaching Interface: *"Poppy the Penguin" coaching system (a) inhale b) exhale). A virtual character named Poppy the Penguin: Teaches and guides patients in breathing techniques; Acts as a coaching/feedback interface*

Biofeedback Mechanism

Physiological data (HR + respiration) is:
Captured in real time
Transmitted via Bluetooth
Integrated into VR gameplay

The system provides closed-loop biofeedback, where:

Correct breathing → physiological targets achieved

Target achievement → game advancement + rewards

Physiological mechanism

Slow breathing → increased heart rate variability (HRV)

Increased HRV → increased vagal tone → reduced pain perception

Platform Overview

Product Components

VR Game-Based Workflow (Core user experience)
Game environment: "Mysterious Island"
- Patients progress through a virtual island by:
- Synchronizing breathing with visual cues
- Maintaining physiological targets

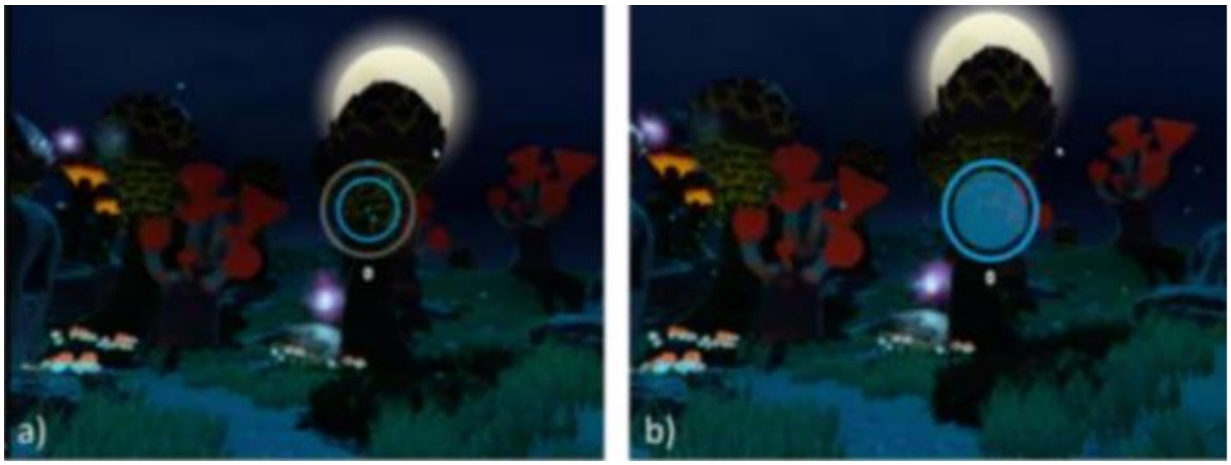
Game mechanics
- Players:
- Move forward on the island when breathing correctly
- Open doors or progress through obstacles using correct breathing patterns
- Earn points for physiological control

Clinical Workflow (How patients use ForeVR)

Patients undergo:
- Preoperative training
- Repeated VR-BF sessions (10-minute structured sessions)

Workflow includes:
- Wearing sensors (ear clip + chest band)
- Using Meta Quest 2 headset
- Performing guided breathing exercises
- Receiving real-time feedback through VR progression

Data recorded:
- Session duration
- HR/respiratory data
- Achievement of physiological targets



Mysterious Island breathing game interaction

Engagement & Gamification System

ForeVR uses gamification principles to enhance adherence:
- Unlockable stages
- Visual customization
- Training progression systems
- Designed to combat boredom seen in prior BF systems

Goal: maintain long-term engagement and repeated use

Platform Overview

Key Differentiators

Key Differentiator	Why Mirawell Health Stands Apart
Real-Time Closed-Loop Biofeedback	Mirawell Health continuously measures physiological signals and uses them to adapt the user experience in real time, creating an active self-regulation pathway rather than a passive distraction experience.
Integrated Breathing and Gameplay	Breathing exercises, visual feedback, navigation, and progression are merged into a single experience, transforming therapy into engaging gameplay rather than a separate clinical task.
Designed Specifically for Pediatric Patients	Built around the needs of children and adolescents, Mirawell Health uses age-appropriate environments, intuitive interactions, and engaging experiences designed to reduce treatment-related stress.
Continuous Breathing Guidance	Persistent visual breathing cues provide ongoing support throughout the session, helping users maintain breathing patterns and remain focused during stressful situations.

Real-Time Biofeedback

•Physiological sensing drives the experience.

Pediatric-First Design

•Built specifically for children and adolescents.

Closed-Loop System

•Measures, adapts, and responds continuously.

VR + Breathing Integration

•Therapy embedded directly into gameplay.

Gamified Self-Regulation

•Rewards healthy coping behaviors.

Platform Overview

Key Differentiators

Key Differentiator	Why Mirawell Health Stands Apart
Gamified Self-Regulation	Progress, rewards, environmental advancement, and gameplay objectives reinforce healthy breathing and coping behaviors while maintaining long-term engagement.
Immersive Therapeutic Environments	Forests, pathways, caves, and evolving virtual landscapes create immersive experiences that help divert attention from the clinical setting while sustaining engagement.
Simple Gaze-Based Interaction	Users can interact through visual focus rather than relying heavily on controllers, reducing complexity and improving accessibility for younger patients.
Familiar Gaming Conventions	Exploration, object collection, progression, and reward mechanisms leverage interaction models already familiar to many adolescents, reducing the learning burden.

Continuous Breathing Guidance

•Always-visible visual coaching.

Objective Physiological Data

•Moves beyond subjective pain scores.

Immersive Therapeutic Environments

•Engaging alternative to clinical settings.

Simple Gaze-Based Interaction

•Minimal learning curve for patients.

Non-Pharmacologic Approach

•Drug-free pain and anxiety support.

Platform Overview

Key Differentiators

Key Differentiator	Why Mirawell Health Stands Apart
Supports Caregivers and Patients	The platform addresses both caregiver and patient needs by promoting engagement, confidence, supervision, and participation throughout treatment.
Objective Physiological Foundation	Unlike traditional supportive-care approaches that rely primarily on subjective symptom reporting, Mirawell Health is designed around physiological monitoring and biofeedback-driven engagement.
Non-Pharmacologic Supportive Care	Mirawell Health offers a drug-free supportive-care approach that aligns with increasing demand for non-pharmacologic pain and anxiety management solutions.
Scalable Clinical Integration Potential	By combining physiological monitoring, biofeedback, immersive VR, and future clinician-facing capabilities, Mirawell Health is positioned to support broader integration within pediatric supportive-care workflows.

Workflow-Friendly Model

- Designed for repeated clinical use.

Scalable Platform Architecture

- Suitable across multiple care settings.

Potential Clinical Dashboard Integration

- Future provider-facing insights.

Built for Longitudinal Use

- Supports ongoing treatment journeys.

Mirawell Health uniquely combines real-time biofeedback, immersive pediatric-focused VR, gamified self-regulation, and physiologically guided engagement into a scalable, non-pharmacologic platform for managing pain, anxiety, and treatment-related stress.

It is a pediatric-focused platform integrating real-time biofeedback, adaptive VR, and gamified self-regulation to support pain, anxiety, and stress management through an engaging, non-pharmacologic experience.

The Mirawell Health Team

Georgia Mitsi, PhD, MBA
CEO

CEO with prior leadership experience across Humana, Biogen, Boehringer Ingelheim, and Sunovion. Leads commercialization, growth strategy, and healthcare innovation.

Vanessa Olbrecht, MD, MBA, FASA
Chief Scientific Officer

Chief Scientific Officer and Chair of Anesthesiology at Nemours Children's Health. Pediatric anesthesiologist and clinical inventor leading clinical strategy and product validation.

Sara Williams, PhD
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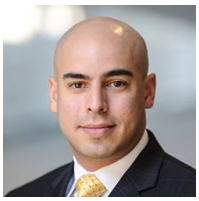
Behavioral Science Advisor and Clinical Professor at Stanford School of Medicine. Expert in pediatric pain psychology, behavioral interventions, and patient engagement.

Christopher King, PhD
Advisor

Clinical Evidence Advisor at Cincinnati Children's Hospital Pediatric Pain Research Center. Leads clinical evidence generation and trial design.

The Mirawell Health Team



Javier Diaz
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Nathan Petts
Engineer

Clinical Engineering Supervisor at Cincinnati Children's Hospital Medical Center

Matthew Batie
Developer

Lead Developer, 3D Printing and Design Services Manager in Digital Experience Technologies Department at Cincinnati Children's Hospital

HITLAB Evaluation Framework

Evaluation Methodology Steps

HITLAB's independent heuristic evaluation and evidence synthesis identified five key themes that collectively support Mirawell Health's potential as a scalable, non-pharmacologic pediatric pain and anxiety management platform.

01: User Engagement Through Therapeutic Design

The heuristic evaluation found that Mirawell Health successfully integrates breathing exercises into an immersive, game-based experience. Continuous breathing guidance, intuitive interactions, and engaging virtual environments help transform relaxation training into an activity that feels interactive rather than clinical.

02: Strong Foundation for Pediatric Supportive Care

HITLAB identified strengths in usability, onboarding structure, visual guidance, and age-appropriate design. The platform demonstrates strong potential to support emotional regulation, reduce treatment-related stress, and improve the overall patient experience for children and adolescents.

03: Demonstrated Clinical Feasibility and Safety

Clinical studies showed high retention, strong adherence, positive satisfaction ratings, and no serious adverse events. These findings support the feasibility of integrating biofeedback-based VR into pediatric care pathways and repeated treatment encounters.

04: Alignment with Emerging Pain Management Trends

The broader evidence base supports a healthcare shift toward non-pharmacologic and opioid-sparing interventions. Multiple external studies demonstrate that VR and biofeedback-based approaches can reduce pain, anxiety, and procedural distress while improving patient engagement.

05: Scalable Platform with Multiple Expansion Pathways

The evidence synthesis identified opportunities beyond pediatric oncology, including pediatric surgery, chronic pain, burn care, rehabilitation, and supportive-care applications. Mirawell Health's combination of physiological monitoring, adaptive VR, and patient engagement creates a scalable platform with broad future potential.

HITLAB Heuristic Evaluation

USER PERSONAS

Persona 1: Parent/Caregiver of an Adolescent Oncology Patient

Emily Carter

Occupation: Working Parent and Primary Caregiver

Age: 42 y

"I want my child to feel calmer and more comfortable, but I need the technology to be simple, safe, and clearly working before we use it during treatment."

Background	**Goals**	**Challenges**
Emily coordinates appointments, treatment schedules, symptom management, school activities, and communication with the care team. She is interested in non-pharmacologic approaches that may help reduce treatment-related stress but needs confidence that the technology is easy to use, safe, and functioning correctly.	• Reduce treatment-related stress and anxiety • Support relaxation around procedures • Set up the system correctly • Monitor whether the intervention is working • Encourage consistent use • Improve the treatment experience	• Managing treatment responsibilities • Supporting a fatigued or anxious child • Understanding hardware and software interactions • Troubleshooting connectivity issues • Confirming physiological signals are being captured
Motivations	**Frustrations**	**Needs**
• Improve comfort during treatment • Reduce procedure-related stress • Support emotional well-being • Encourage healthy coping strategies • Increase the child's sense of control	• Complex setup processes • Technical failures • Unclear feedback and instructions • Limited caregiver reporting • Lack of guidance during troubleshooting	• Simple setup guidance • Clear connection status indicators • Easy troubleshooting support • Caregiver-facing session information • Safety and comfort guidance

HITLAB Heuristic Evaluation

USER PERSONAS

Persona 2: Adolescent Oncology Patient

Daniel Carter

Occupation: High School Student

Age: 15 y

"I want something that helps me relax without making me feel like I'm doing another medical procedure."

Background Daniel is a 15-year-old undergoing oncology treatment. Frequent appointments, procedures, and treatment-related stress affect daily life. He is comfortable with technology and prefers experiences that feel engaging and interactive rather than clinical.	**Goals** • Feel calmer during treatment • Reduce anxiety around procedures • Enjoy the experience • Use the system independently • Complete activities successfully • Feel more in control	**Challenges** • Treatment-related fatigue and discomfort • Difficulty concentrating when stressed • Wearing equipment comfortably • Understanding written instructions • Managing frustration during technical failures
Motivations • Interactive experiences • Game-like environments • Visual rewards and progression • Independence and autonomy • Feeling successful and in control • Escaping the clinical environment temporarily	**Frustrations** • Long written instructions • Complicated navigation • Technical issues interrupting gameplay • Having to restart experiences • Unclear controls • Lack of pause or recovery options	**Needs** • Voice-guided instructions • Clear visual feedback • Simple controls • Intuitive navigation • Save, pause, and resume functionality • Age-appropriate design • Comfortable, engaging experiences

HITLAB Heuristic Evaluation

HITLAB conducted an independent heuristic evaluation of the Mirawell Health platform to assess usability, accessibility, workflow integration, and overall user experience for pediatric patients and caregivers. The evaluation identified a strong foundation for engagement and supportive care delivery, while also highlighting several opportunities to further strengthen scalability, usability, and real-world clinical adoption

Key Observations

- **Engaging Therapeutic Experience:** Mirawell Health successfully combines breathing exercises, visual feedback, and gameplay progression into a single immersive experience. Continuous breathing guidance and game-based interactions help make therapeutic activities feel engaging rather than clinical.
- **Strong Pediatric-Centered Design: The** platform leverages familiar gaming mechanics, intuitive navigation, gaze-based interactions, and immersive environments that are well aligned with adolescent preferences and engagement needs.
- **Clear Guidance and Progress Feedback:** Visual breathing cues, orb collection, gameplay objectives, and progression indicators provide users with continuous feedback and a clear sense of achievement throughout each session.
- **Opportunity to Enhance Biofeedback Visibility:** The platform introduces a compelling real-time biofeedback concept. Additional visibility into sensor status and active physiological feedback could further strengthen user confidence and caregiver trust.
- **Opportunity to Strengthen Clinical Scalability:** Further enhancements in onboarding, audio guidance, caregiver reporting, and session continuity may support broader adoption and smoother integration into clinical workflows.

Mirawell Health demonstrates a differentiated approach by combining immersive VR, guided breathing, and physiological self-regulation within a child-friendly experience. Its strongest strengths lie in engagement, accessibility, and the ability to transform therapeutic activities into interactive experiences. The platform is well aligned with the growing demand for non-pharmacologic pediatric pain and anxiety management solutions. Opportunities to further strengthen connectivity visibility, caregiver support, and workflow simplicity may enhance adoption across healthcare settings. Mirawell Health's combination of biofeedback, gamification, immersive environments, and pediatric-focused design creates a scalable foundation for supportive-care applications across oncology, perioperative care, and procedural anxiety management.

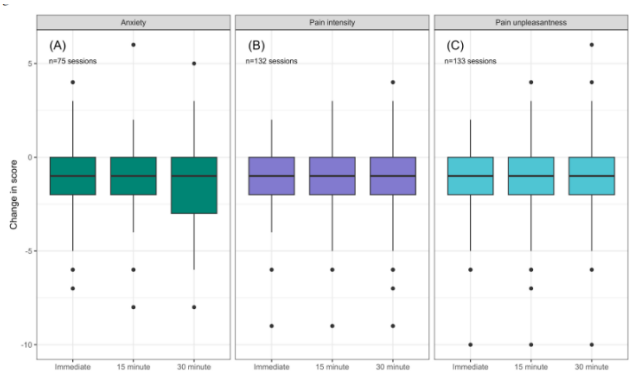
Clinical Outcome Evidence

Biofeedback-Based Virtual Reality for Pediatric Surgery: Feasibility, Acceptability, and Early Pain and Anxiety Outcomes

This pilot randomized controlled trial evaluated the feasibility, acceptability, and preliminary clinical performance of ForeVR, a biofeedback-based virtual reality intervention, in adolescents undergoing surgery. Participants were randomized to either ForeVR or the active control application, Manage My Pain, during the perioperative period. The primary objective was to assess recruitment, retention, adherence, and participant acceptance before conducting future efficacy trials (Lin et al., 2026).

Key Findings

- 202 of 219 screened patients (92.2%) met eligibility criteria.70 participants enrolled and 65 completed the trial, resulting in a 92.9% retention rate.91.4% completed preoperative sessions and 85.7% completed postoperative sessions.
- Participants completed a median of 4 preoperative training sessions and 7 postoperative sessions.76.7% of patients and 85.7% of caregivers reported satisfaction with ForeVR.56.7% reported feeling calmer, while 46.7% believed the intervention reduced pain.
- No serious adverse events occurred; reported side effects were mild and transient.
- Participants with baseline pain or anxiety scores ≥2 demonstrated clinically meaningful median reductions of approximately 1 point in pain intensity, pain unpleasantness, and anxiety following VR-BF sessions.
- Participants reported applying breathing techniques learned through ForeVR outside of VR sessions, suggesting transfer of self-regulation skills into recovery settings.



Changes in anxiety, pain intensity, and pain unpleasantness following ForeVR sessions. Participants with baseline symptoms ≥2 demonstrated clinically meaningful reductions in pain and anxiety immediately after VR-biofeedback use, with improvements maintained for up to 30 minutes.

This pilot randomized trial demonstrated that perioperative biofeedback-based virtual reality is feasible, acceptable, and generally well tolerated among adolescents undergoing surgery.

High recruitment, retention, adherence, and satisfaction support further investigation in larger clinical trials designed to evaluate pain reduction, anxiety management, and opioid-sparing outcomes.

Clinical Outcome Evidence

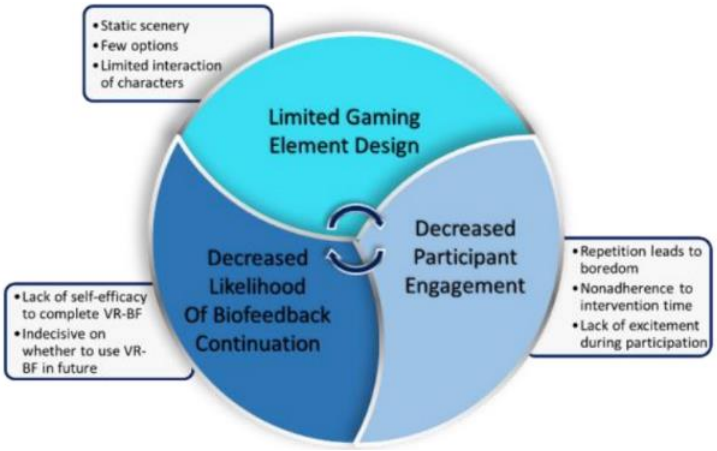
ForeVR: A Gamified VR Biofeedback Device for Postoperative Pain Management

The study presents evidence for ForeVR, a virtual reality–based biofeedback (VR-BF) device that integrates real-time heart rate variability and respiratory rate monitoring into a gamified VR environment designed to reduce postoperative pain and opioid use in children and adolescents. The evidence includes feasibility and preliminary performance data from pilot and R34 studies, along with proposed validation and clinical efficacy trials.

ForeVR device

Key Findings

- The ForeVR system combines VR immersion with real-time physiological biofeedback (heart rate variability and respiratory rate) to train patients in slow breathing and autonomic regulation for pain reduction.
- Pilot R34 feasibility data in 23 surgical adolescents showed high engagement and acceptability, including 91% overall retention, 87% preoperative session completion, 70% postoperative completion, and strong usability ratings (e.g., 95% reported ease of use, 80% satisfaction/happiness).
- Patients were able to use the system independently, including at-home use, with 43% continuing use after discharge, indicating real-world usability beyond supervised settings.
- Preliminary device performance testing (n=4) showed respiratory rate estimates from ForeVR closely aligned with a clinical monitor (average difference ~0.71 breaths/min), suggesting initial signal validity but requiring larger validation.



Engagement findings from pilot work

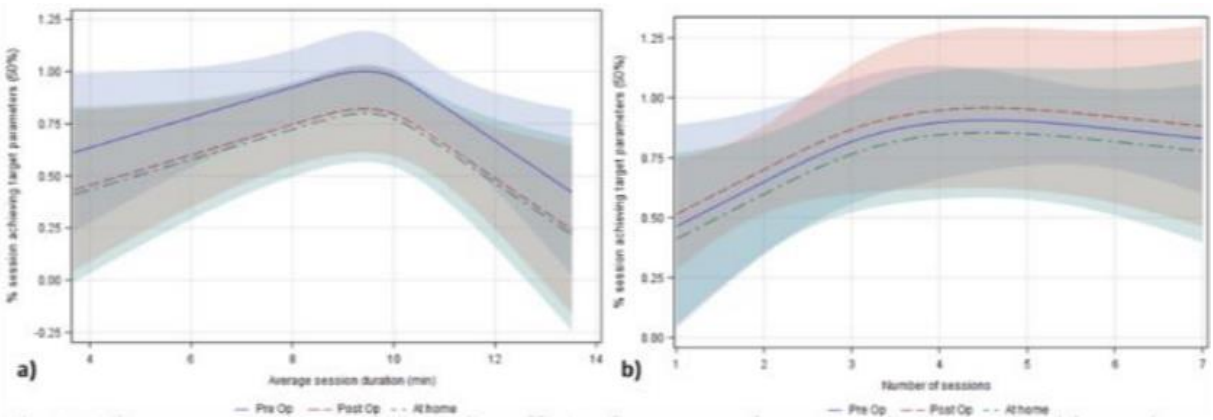
Source: Mirawell Health

- Preliminary device performance testing (n=4) showed respiratory rate estimates from ForeVR closely aligned with a clinical monitor (average difference ~0.71 breaths/min), suggesting initial signal validity but requiring larger validation.
- Preliminary findings indicated patients could achieve target physiological control (>50% of session time in target range), but performance was lower postoperatively (e.g., 67% preoperative vs 25% postoperative for >80% target HRV attainment), suggesting context-dependent efficacy.
- Supporting rationale from pilot interviews indicated that lack of engagement in earlier versions reduced adherence, directly motivating the development of enhanced gamified VR content.
- Across prior VR-BF literature cited in the document, VR-based biofeedback is associated with improved engagement, motivation, and adherence compared with non-VR biofeedback, supporting the device's design rationale.

Clinical Outcome Evidence

Virtual Reality Biofeedback Improves Engagement and Self-Regulation

Traditional biofeedback therapies have demonstrated benefits for pain management but are often limited by low engagement, specialized equipment requirements, and dependence on trained personnel. ForeVR was developed to address these limitations by combining real-time biofeedback, immersive virtual reality, and gamified reinforcement into a more engaging pediatric intervention.



HRV achievement results: (a) Relationship between average session duration (minutes) and achievement of target HRV parameters. (b) Relationship between number of sessions completed and achievement of target HRV parameters.

Key Findings

- 91% overall protocol completion (21/23 participants).
- 87% completed preoperative training sessions.70% completed postoperative sessions.
- 43% continued using the platform at home after discharge.
- 95% achieved target HRV coherence during at least one session.
- 90% reported receiving good instructions.95% reported the system was easy to use.80% reported satisfaction with the experience.
- Approximately 10-minute sessions produced the highest probability of achieving physiologic targets.
- Approximately 4–5 sessions maximized HRV target achievement.
- Participants reported the experience was calming and helpful between medication doses.

ForeVR demonstrated high acceptability, strong usability, and successful physiologic training among adolescents. The findings suggest that approximately 10-minute sessions delivered across 4–5 training exposures may optimize biofeedback performance and patient engagement.

Source: Mirawell Health

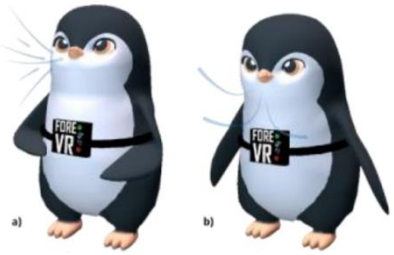
Clinical Outcome Evidence

ForeVR Innovation and Clinical Validation Roadmap

ForeVR was developed as an integrated pediatric VR-biofeedback platform that combines respiratory monitoring, HRV biofeedback, gamification, and real-time physiologic adaptation. The proposed validation program is designed to support future multicenter efficacy trials focused on pain reduction and opioid-sparing care.

Key Findings

- 30 adolescents planned for physiologic validation testing against ECG and capnography standards.
- 40 adolescents planned for user-centered design, focus groups, and engagement optimization.128 adolescents planned for a randomized pilot efficacy trial.
- Recruitment target: 5–6 patients per month.
- Feasibility benchmark: ≥80% retention.
- Adherence benchmark: ≥80% protocol completion.
- Safety benchmark: <1% adverse events.
- Statistical power target: 80% power to detect moderate treatment effects (d=0.5).
- Target physiologic validation threshold: Heart-rate correlation ≥0.90 versus ECG.
- Respiratory target: Within 3 breaths/minute of capnography reference.
- ForeVR captures adherence, HRV achievement, respiratory performance, and duration of use.



User Training & Coaching Interface

The ForeVR development pathway incorporates physiologic validation, user-centered design, and randomized clinical evaluation. The proposed program establishes a structured framework for future multicenter studies assessing pain reduction, opioid use, engagement, and long-term clinical adoption.

Additional Insights:

- Greater engagement and repeated use improved physiologic target achievement.
- Skills learned in VR are intended to transfer beyond the virtual environment.
- ForeVR uniquely combines respiratory biofeedback, HRV biofeedback, adaptive VR, and gamified reinforcement in a pediatric-focused platform.

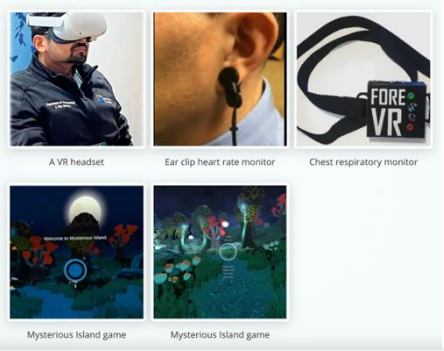
Source: Mirawell Health

Clinical Outcome Evidence

IslandVR Consumer Survey Results

Aim: Gauge consumer interest and pricing preference for IslandVR among people experiencing pain, anxiety, or both.

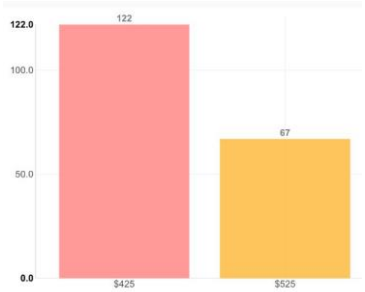
Methodology: Screened survey of participants with pain/anxiety (~110–209 respondents); demographic and tech-ownership questions, a 1–5 likelihood-of-use scale, package/pricing choices, purchase-model preference, and open-ended concerns.



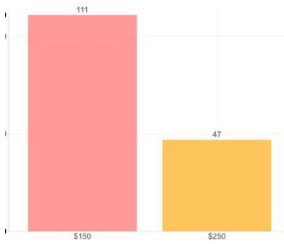
Survey results:

- 61% female, 39% male
- 54% own a fitness tracker; 72% play games (27% on PC/console)
- Only ~9% have VR exposure; 21.5% own a VR headset
- 67% selected Package A; price anchors at $100 and $150, ceiling $425
- 48% (97) preferred a one-time game purchase; 65% (143) a one-time hardware purchase
- Concerns: bulky headset, flimsy earlobe monitor, dark/childish graphics, price

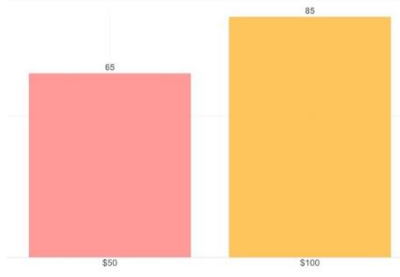
- Genuine interest from a game-friendly but VR-inexperienced audience.
- 48% (97 participants) chose one time payment of the game
- 67% selected Package A; highest price willingness to pay: $425



Package A ($425: selected 67% participants)



Package B ($150)



Package C ($100)

Package options with Highest price willing to pay

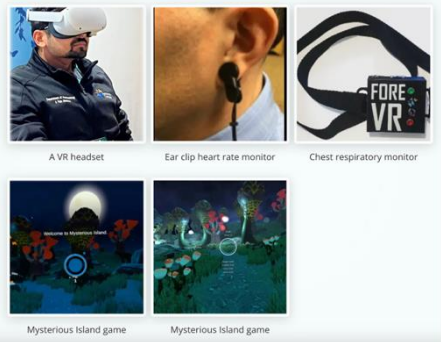
Source: Mirawell Health

Clinical Outcome Evidence

IslandVR Hospice Care Survey Results

Aim: Understand how IslandVR could be used in hospice care settings.

Methodology: Survey of ~115 hospice stakeholders across caregiver, administrative, clinical, and emotional-support roles; 1–5 scales for user-friendliness and comfort, estimated patient applicability, plus questions on features, training resources, setup assistance, clinical data needs, and feasibility concerns..



Survey results:

- 47% caregivers (family/friend), 37% administrative, 10% clinical, 6% emotional support
- Estimated applicability to hospice patients clustered at 20–40% and 40–60%
- Usability and comfort are already good — both the "user-friendly" and "comfortable" ratings peak at 4 out of 5, with very few 1s, so the headset experience isn't the barrier
- Roughly half of hospice patients are seen as suitable — top answer 40–60% (42 votes), with 20–40% close behind at 39; only 15 votes total sit at the two extremes
- Quick set-up is the make-or-break feature — scored 100, far ahead of small space requirements (62), multi-patient sharing (55) and accessible data (51)
- Self-serve training wins — a video how-to guide (89) beats virtual (73) and on-site (72) demonstrations, with the written user manual last (57)
- Clinical caregivers lead adoption, family close behind — 64 vs 59, so the workflow has to work for both
- Anxiety-reduction evidence carries the most weight — 84, ahead of quality-of-life (79) and pain reduction (66); all three matter, none is dismissed

- Hospice stakeholders see real but partial applicability — roughly a third to half of patients.
- Adoption depends on caregiver-assisted simplicity, lighter and more comfortable hardware, calmer content, and clinical evidence of safety and effectiveness.
- Respondents rate IslandVR as usable and comfortable (mostly 4/5) and see it fitting roughly half of hospice patients.
- Adoption hinges on quick set-up above all other features, delivered through self-serve video training, with clinical caregivers — closely followed by family — doing the assisting, and anxiety-reduction evidence carrying the most weight.

Source: Mirawell Health

Clinical Outcome Evidence

Stakeholder Evidence Synthesis: Clinical Interest, Adoption Drivers and Implementation Barriers for IslandVR

Stakeholder interviews across pediatric hospitals, academic medical centers, behavioral health organizations and healthcare innovation leaders demonstrate strong interest in IslandVR as a non-pharmacological intervention for pain, anxiety and self-regulation. While respondents recognized the clinical potential of immersive biofeedback, they consistently emphasized that successful adoption will depend on demonstrating measurable outcomes, ease of implementation and seamless integration into existing clinical workflows.

Evidence Theme	Key Findings	Representative Stakeholders	Implications for IslandVR
Strong demand for non-pharmacological pain management	Multiple stakeholders expressed interest in alternatives to opioids, sedatives and medication-intensive symptom management approaches, particularly in pediatric populations.	Katherine Deans, MD, MHSc; Victor Garcia, MD, FACS, FAAP; Richard "Scott" Adams, BSN	Positions IslandVR within the growing movement toward non-pharmacological and behavioral approaches to pain management.
Pediatric perioperative care emerged as the strongest beachhead market	Stakeholders repeatedly identified pre-surgical anxiety, surgical preparation, pain education and post-operative recovery as ideal use cases. Several experts recommended introducing the intervention before surgery rather than after symptoms develop.	Sara Williams, PhD; Victor Garcia, MD, FACS, FAAP; Derek Wheeler, MD, MMM, MBA	Pediatric surgery programmes represent the most clearly defined initial market opportunity.
Breathing biofeedback is viewed as clinically valuable but difficult to teach	Behavioral health and pediatric pain experts noted that breathing techniques are effective but patients struggle with engagement, adherence and correct execution.	Sara Williams, PhD; Taylor Matheson, MSN, PMHNP; Lori Lycans, MSW, LSW	IslandVR's integration of breathing biofeedback with immersive engagement addresses a recognized gap in current care models.
Biofeedback combined with VR is perceived as differentiated	Experts reported limited awareness of existing products that combine respiratory biofeedback, physiological monitoring and immersive VR in a patient-friendly experience.	Sara Williams, PhD; Nicole Zakha, PhD	Creates a potentially distinctive position relative to traditional biofeedback systems and passive VR distraction tools.
Patient engagement and gamification are major strengths	Stakeholders believed children are more likely to engage with interventions that provide feedback, control, choice and play-based experiences.	Scott Shaw; Nicole Zakha, PhD; Sara Williams, PhD	Supports the use of gamification as a core product design and adoption strategy.

Clinical Outcome Evidence

Evidence Theme	Key Findings	Representative Stakeholders	Implications for IslandVR
Potential applications extend beyond pain management	Interviewees identified opportunities in anxiety, stress reduction, addiction recovery, chronic pain syndromes, functional neurological disorders, GI disorders and behavioral health.	Lori Lycans, MSW, LSW; Taylor Matheson, MSN, PMHNP; Nicole Zakha, PhD; Sara Williams, PhD	Indicates future expansion opportunities after establishing credibility in perioperative care.
Strong interest in oncology and supportive-care applications	Stakeholders involved in cancer and supportive care viewed gamified VR and biofeedback positively as adjunctive symptom-management tools.	Richard "Scott" Adams, BSN	Represents a secondary market opportunity for future clinical validation studies.
Workflow integration is the primary adoption barrier	Respondents consistently warned that hospitals have limited capacity for solutions requiring additional staffing, training or infrastructure.	Joseph Cravero, MD; Derek Wheeler, MD, MMM, MBA; Scott Shaw	Product simplicity may be as important as clinical effectiveness in determining adoption success.
Ease of use is essential for clinicians and patients	Stakeholders emphasized simple onboarding, intuitive interfaces, minimal setup requirements and low maintenance burdens.	Joseph Cravero, MD; Scott Shaw; Richard "Scott" Adams, BSN	User-centered design and operational simplicity should remain key development priorities.
Clinical champions will be necessary for implementation	Interviewees identified pain services, anesthesia, psychology, Child Life and nursing leaders as likely champions for adoption.	Joseph Cravero, MD; Katherine Deans, MD, MHSc; Derek Wheeler, MD, MMM, MBA	Commercial strategy should focus on recruiting departmental champions during pilots.
Evidence generation is required before broad adoption	Hospital executives requested measurable outcomes demonstrating patient benefit and operational value.	Derek Wheeler, MD, MMM, MBA; Tony Johnston; Todd A. Ponsky, MD	Robust pilot studies and real-world evidence generation will be critical for scale-up.
Outcome measures should include both clinical and operational metrics	Suggested indicators included pain reduction, opioid reduction, patient satisfaction, length of stay, readmissions and cost-effectiveness.	Tony Johnston; Derek Wheeler, MD, MMM, MBA; Katherine Deans, MD, MHSc	Future studies should incorporate health-economic as well as clinical endpoints.

Clinical Outcome Evidence

Evidence Theme	Key Findings	Representative Stakeholders	Implications for IslandVR
Flexible purchasing models may be needed	Stakeholders discussed capital purchases, subscriptions, departmental budgets, philanthropy and grants as potential funding pathways.	Tony Johnston; Joseph Cravero, MD; Garret Goody; Scott Shaw	A hybrid commercial model may improve adoption across different healthcare settings.
Home use is viewed as promising but operationally challenging	Respondents liked the idea of extending therapy beyond the hospital but raised concerns regarding equipment loss, management and affordability.	Garret Goody; Taylor Matheson, MSN, PMHNP; Lori Lycans, MSW, LSW	Initial deployment may be most feasible within supervised clinical environments.

Overall, stakeholders identified pediatric perioperative care as the most promising initial market, citing opportunities to improve pain management, reduce anxiety and strengthen patient engagement through breathing biofeedback and immersive experiences. At the same time, respondents repeatedly noted that evidence generation, workflow fit, operational simplicity and a clear value proposition will be critical determinants of adoption within healthcare systems.

Extended Validation

Guided Relaxation-Based Virtual Reality for Acute Postoperative Pain and Anxiety in a Pediatric Population

In this pilot observational study (Olbrecht et al., 2021), 51 children and adolescents (7–21 years) with moderate-to-severe postoperative pain underwent a single 10-minute guided relaxation-based virtual reality (VR-GR) session using the "Mindful Aurora" application. The study assessed changes in pain intensity, pain unpleasantness, and anxiety following VR-GR, while exploring the influence of pain catastrophizing and anxiety sensitivity on these outcomes. Results showed significant reductions in all three measures immediately post-session, with pain unpleasantness reductions sustained at 30 minutes. Higher anxiety sensitivity was associated with greater pain reduction, and 96% of participants would recommend VR to others, with zero reported side effects.

Key Findings

- **Significant Pain Intensity Reduction:** Pain intensity decreased immediately post-VR (median -1.0, IQR -2.0 to 0, $p < 0.001$) and remained lower at 30 minutes ($p = 0.02$), though not at 15 minutes ($p = 0.16$) when assessed with Bonferroni correction.
- **Sustained Pain Unpleasantness Reduction:** Pain unpleasantness decreased significantly at all time points—immediately (median -2.0, $p < 0.001$), at 15 minutes (median -1.0, $p < 0.001$), and at 30 minutes (median -1.0, $p < 0.001$)—demonstrating the most durable effect.
- **Transient Anxiety Reduction:** Anxiety decreased immediately post-VR (median 0, IQR -1.0 to 0, $p < 0.001$) and at 15 minutes ($p = 0.01$), but returned to baseline by 30 minutes ($p = 0.17$).
- **Anxiety Sensitivity as a Predictor:** Patients with higher Child Anxiety Sensitivity Index (CASI) scores experienced significantly greater reductions in pain intensity ($\beta = -0.06$, SE 0.03, $p = 0.04$) and pain unpleasantness ($\beta = -0.09$, SE 0.04, $p = 0.01$) following VR-GR.
- **Pain Catastrophizing Not Associated:** Pain Catastrophizing Scale for Children (PCS-C) scores did not predict changes in pain intensity, pain unpleasantness, or anxiety (all $p > 0.05$).
- **High Patient Satisfaction:** 96% (49/51) of children would recommend VR to friends and family; 88% (45/51) reported feeling calmer and less anxious; 88% believed VR made it easier to tolerate pain.
- **Zero Adverse Events:** No patient experienced any self-reported side effects (dizziness, nausea, or discomfort) during or after the VR session.

A single 10-minute guided relaxation-based virtual reality session significantly reduced postoperative pain intensity, pain unpleasantness, and anxiety in children, with high patient satisfaction, zero side effects, and greater benefits for those with higher anxiety sensitivity.

This study demonstrates that pediatric patients not only accept but actively embrace and benefit from VR-based non-pharmacological pain management, with 96% recommending the technology to others.

Mirawell Health Islander's directly addresses the critical need identified in this research—making evidence-based, engaging, and accessible digital therapeutics available to children and families, reducing reliance on opioids while empowering patients with self-directed pain relief tools that work.

Extended Validation

Treatment Protocol of a Biofeedback-Based Virtual Reality Intervention for Pain and Anxiety in Children and Adolescents Undergoing Surgery

Orgil et al., 2023 presented a 23-patient dataset from a prospective, single-center study designed to refine a perioperative treatment protocol for biofeedback-based virtual reality (VR-BF) in adolescents undergoing surgery. Participants (12–18 years) used a Meta Quest 2 headset with the Mindfulness Aurora application and HeartMath Inner Balance device to complete daily 10-minute VR-BF sessions preoperatively, postoperatively, and optionally at home. The dataset establishes measurable outcomes—including heart rate variability (HRV) coherence targets—and qualitative patient/family feedback to inform a future randomized controlled trial.

Key Findings

- **Overall adherence:** 21/23 (91%) completed VR-BF sessions; median 9 sessions (IQR 6–10); mean session duration 9.5 ± 1.9 min; 20/21 (95%) achieved target HRV coherence ≥50% of session time.
- **Preoperative phase:** 20/23 (87%) completed sessions; median 6 sessions (IQR 4–7); 19/20 (95%) achieved target HRV coherence.
- **Postoperative phase:** 16/23 (70%) completed sessions; median 2 sessions (IQR 1–2.5); 13/16 (81%) achieved target HRV coherence.
- **Home phase:** 10/23 (43%) completed sessions; median 2.5 sessions (IQR 2–4); 8/10 (80%) achieved target HRV coherence.
- **Optimal dosing signals:** Spline regression models suggest ~10-minute sessions and ~4–5 total sessions maximize the percentage of sessions achieving target HRV parameters.
- **Patient/family experience:** 20 patients (87%) and 19 parents (83%) completed surveys; responses indicated high acceptability, satisfaction, and perceived benefit, with most willing to recommend and use VR-BF again.
- **Data utility:** The dataset supports refinement of VR-BF dosing and informs the design of a future efficacy trial assessing pain, anxiety, and opioid consumption in pediatric surgical patients.

Biofeedback-based virtual reality is feasible and acceptable in adolescents, with 10-minute sessions and approximately 4–5 sessions optimizing HRV coherence targets, informing future randomized trial design.

This dataset reinforces the promise of immersive, biofeedback-integrated VR for pediatric perioperative pain and anxiety, aligning with Mirawell Health Health's mission to deliver evidence-based, accessible digital therapeutics. By translating such feasibility data into scalable, engaging solutions,

Mirawell Health Islander's can help bring nonpharmacologic pain care to children and families.

Extended Validation

Pediatric Pain Management: From Regional to Virtual

This review current trends and recent developments in regional anesthesia and virtual reality (VR) for pediatric pain management. The article discusses the growing role of fascial plane blocks, spinal and continuous epidural anesthesia in infants, and the emerging evidence for VR—including distraction-based and biofeedback/guided-relaxation-based modalities—in reducing pediatric pain and anxiety. While regional anesthesia is well established, VR remains a promising but nascent field requiring larger, rigorous trials before widespread adoption (Heydinger et al., 2023).

Key Findings

- Regional anesthesia is expanding in pediatrics due to opioid-sparing multimodal strategies and concerns about neurocognitive effects of general anesthesia.
- Novel fascial plane blocks (e.g., quadratus lumborum, erector spinae) provide effective analgesia and reduce opioid consumption; quadratus lumborum block is superior to TAP and ilioinguinal/iliohypogastric blocks for inguinal hernia repair.
- Spinal anesthesia in infants confers hemodynamic stability, avoids airway instrumentation, and reduces postoperative apnea; clonidine prolongs blockade with minimal side effects.
- Continuous epidural analgesia in infants, especially with 2-chloroprocaine, decreases opioid exposure and time to tracheal extubation (3.2 vs. 19.7 mg/kg opioid; 1.3 vs. 3.2 days extubation).
- Virtual reality for pain management relies on immersion, sensory feedback, and interactivity; mechanisms include distraction and integration with biofeedback/guided relaxation.
- VR has shown efficacy in adults for acute and chronic pain, and emerging pediatric evidence supports reducing pain and anxiety during procedures, with mixed results for postoperative pain.
- VR-GR and VR-BF (guided relaxation and biofeedback) show promise for transient reductions in pain and anxiety in children after surgery, but large-scale randomized controlled trials are needed.

Regional anesthesia techniques and virtual reality are both valuable, evolving tools for pediatric pain management, with VR showing promise but requiring further rigorous study before widespread adoption.

Mirawell Health Health's commitment to evidence-based digital therapeutics directly aligns with this review's call for innovative, nonpharmacological pediatric pain solutions. By advancing accessible, engaging VR-based interventions, Mirawell Health Islander's can help bridge the evidence gap and bring effective, opioid-sparing pain relief to children and families.

Extended Validation

Transient Reductions in Postoperative Pain and Anxiety with the Use of Virtual Reality in Children

In this single-center, prospective pilot study (Olbrecht et al., Pain Medicine, 2021), 50 children and adolescents (7–21 years) with postoperative pain following major surgery underwent a single distraction-based virtual reality (VR-D) session. The study assessed changes in pain intensity (primary outcome), pain unpleasantness, and anxiety immediately, at 15 minutes, and at 30 minutes after VR-D, and explored whether pain catastrophizing (PCS-C) or anxiety sensitivity (CASI) influenced outcomes. Results showed significant transient reductions in pain intensity, pain unpleasantness, and anxiety, with pain unpleasantness reductions sustained up to 30 minutes. Patient satisfaction was high, with no adverse effects reported. The findings support VR-D as a promising nonpharmacologic adjunct for acute postoperative pain management in children and inform the design of future randomized controlled trials.

Key Findings

- Primary outcome – pain intensity: VR-D significantly reduced pain intensity immediately (median -1.00, IQR -2.00 to 0, $p < 0.0001$) and at 15 minutes (median 0, IQR -1.00 to 0, $p = 0.02$), but not at 30 minutes. After covariate adjustment, only the immediate reduction remained significant.
- Secondary outcome – pain unpleasantness: VR-D significantly reduced pain unpleasantness immediately (median -1.00, IQR -2.50 to 0, $p < 0.0001$), at 15 minutes (median -1.00, IQR -2.00 to 0, $p = 0.0008$), and at 30 minutes (median -1.00, IQR -2.00 to 0, $p = 0.0001$). Adjusted models confirmed significance at all time points.
- Secondary outcome – anxiety: VR-D significantly reduced anxiety immediately (median 0, IQR -1.00 to 0, $p < 0.0001$) and at 15 minutes (median 0, IQR -1.50 to 0, $p = 0.0014$), but not at 30 minutes. Adjusted models showed no significant changes.
- Psychological factors: Higher pain catastrophizing was associated with higher baseline pain intensity and unpleasantness, but neither pain catastrophizing nor anxiety sensitivity influenced the magnitude of pain reduction after VR-D.
- Patient satisfaction: 94% of children would recommend VR to friends and family; 87.5% felt calmer and less anxious; 87.5% believed VR made it easier to tolerate pain. Parents similarly reported high satisfaction (95% would recommend). No adverse effects were reported.
- VR session details: Mean VR experience time was 14.6 ± 4.46 minutes; patients chose from multiple nonviolent, engaging VR experiences (e.g., Ocean Rift, Space Pups, Wonderglade).

A single session of distraction-based VR produced transient, clinically meaningful reductions in postoperative pain unpleasantness and smaller reductions in pain intensity and anxiety in children, with high satisfaction and no adverse effects.

Immersive VR can safely and effectively reduce postoperative pain and anxiety in children, highlighting the potential of digital therapeutics to transform pediatric pain care. Mirawell Health randomized is uniquely positioned to advance this field by delivering accessible, evidence-based VR interventions that empower young patients and reduce reliance on opioids.

Extended Validation

Biofeedback-Based Virtual Reality for Pediatric Surgery: Feasibility, Acceptability, and Early Pain and Anxiety Outcomes

Lin et al., 2026 conducted a pilot randomized controlled trial evaluating perioperative biofeedback-based virtual reality (VR-BF) in adolescents undergoing surgery. The study compared the ForeVR breathing and biofeedback intervention with the Manage My Pain app, focusing primarily on feasibility, acceptability, adherence, and safety rather than definitive clinical efficacy.

Key Findings

- 70 participants enrolled, and 65 completed the study, giving a 92.9% retention rate.
- Participants had a median age of 16.2 years, and 58.6% were female.
- 91.4% completed at least one preoperative session, while 85.7% completed at least one postoperative session.
- VR-BF participants completed a median of four preoperative sessions and seven sessions overall.
- 76.7% of patients and 85.7% of caregivers reported being pleased with VR-BF.
- More than half of participants reported feeling calmer, and nearly half believed VR-BF reduced their pain.
- Among participants with baseline symptoms above 2/10, median pain intensity, pain unpleasantness, and anxiety each decreased by approximately one point after VR-BF use.
- Symptom improvements were observed for up to 30 minutes after a session, but these were exploratory within-session findings.
- There were no serious adverse events. Reported effects—including headache, nausea, and dizziness—were mild and temporary.
- Technical problems with the prototype limited physiological data collection and affected some adherence.
- The pilot wasn't powered for between-group efficacy comparisons, so it doesn't establish that VR-BF is more effective than the control intervention.

This pilot trial found perioperative VR biofeedback feasible, acceptable, and generally safe for adolescents, with promising—but not yet definitive—signals of short-term pain and anxiety reduction.

The trial supports Mirawell Health's model by showing that immersive, biofeedback-guided breathing can be integrated into perioperative care with strong retention, adherence, and patient-caregiver acceptance.
Its preliminary symptom improvements strengthen the rationale for Mirawell Health as a nonpharmacological complement to multimodal pain care, while reinforcing the need for a larger efficacy trial and reliable physiological monitoring.

Extended Validation

Biofeedback-Based Virtual Reality Shows Promise for Calmer Pediatric Surgical Care

Pain and anxiety can make surgery especially challenging for children and adolescents, creating a need for safe, nonpharmacologic approaches to perioperative support. Orgil et al., 2024 examined whether virtual reality combined with paced-breathing biofeedback could help pediatric surgical patients regulate stress through improved heart rate variability (HRV) coherence.

Key Findings

- Feasible before surgery: 87% of participants completed at least one preoperative session.
- Strong physiological engagement: 95% of preoperative users achieved the target HRV coherence during at least one session.
- Optimal protocol: The highest probability of HRV success was associated with 4–6 sessions lasting 9–10 minutes.
- Easy to use: 95% found the system easy to use, and all participants understood the instructions.
- Calming experience: 85% reported feeling calmer or experiencing reduced stress.
- Limited evidence for pain relief: Only 40% perceived a reduction in pain, and the study didn't directly measure pain, anxiety, or opioid consumption.
- Generally well tolerated: Two participants reported mild headache or nausea; no serious adverse events occurred.
- Engagement needs improvement: Use declined after discharge, with some participants describing the VR content as insufficiently engaging.

Most participants reported a calming effect, but evidence for pain relief was limited and adherence decreased after discharge. Because the study was small, had no control group, and focused on protocol development rather than clinical efficacy, randomized trials are needed to determine whether VR biofeedback reduces pain, anxiety, or opioid use.

The study supports Mirawell Health's focus on technology-enabled, nonpharmacologic experiences that may help pediatric patients manage perioperative stress.
It also highlights opportunities to combine biofeedback with more engaging, personalized VR content while validating clinical benefits through controlled research.

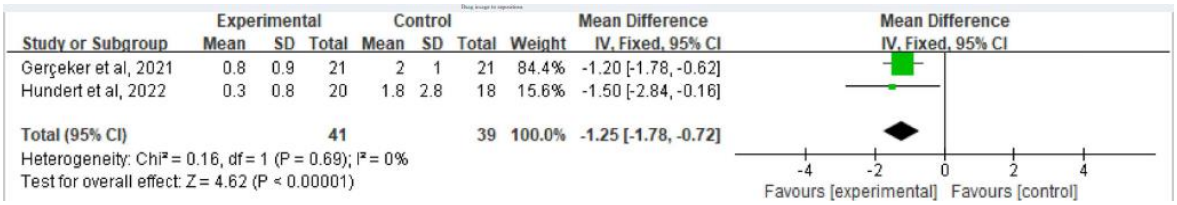
Extended Validation

Virtual Reality for Pain and Anxiety in Pediatric Oncology

This study evaluated randomized controlled trials examining the effects of virtual reality on pain, anxiety, and fear among children with cancer. This study provides the most directly relevant independent evidence for Mirawell Health's initial pediatric oncology use case (Cheng et al., 2022). Children undergoing cancer treatment experience repeated painful and anxiety-provoking procedures such as venipuncture, bone marrow aspiration, lumbar puncture, and chemotherapy administration. This systematic review and meta-analysis evaluated whether virtual reality could reduce pain, anxiety, and fear in pediatric oncology patients.

Key Findings

- The review included six randomized controlled trials involving 379 children with cancer.
- VR significantly favored control conditions for pain, with a mean difference of −4.82 and a 95% confidence interval of −7.74 to −1.89.VR significantly favored control conditions for anxiety, with a standardized mean difference of −1.47 and a 95% confidence interval of −2.46 to −0.48.
- Pain and anxiety analyses showed high heterogeneity, at 95% and 92%, respectively.
- The study also reported improvement in fear, but the numerical estimate should be interpreted cautiously because the reported confidence interval and P value appear internally inconsistent.
- Virtual reality significantly reduced pain compared with control interventions.
- Virtual reality significantly reduced anxiety compared with standard care.
- Findings generally favored VR for fear reduction, although larger studies are still needed.
- Authors concluded that VR is beneficial for improving pain and anxiety outcomes in pediatric cancer patients.



Forest plot for virtual reality on fear.

This study supports pediatric oncology as a priority use case for Mirawell Health, particularly during recurring procedures such as venipuncture, port access, lumbar puncture, and bone marrow procedures. Future Mirawell Health studies should use standardized protocols, validated outcome measures, and procedure-specific analyses due to the substantial heterogeneity in the existing evidence.

Extended Validation

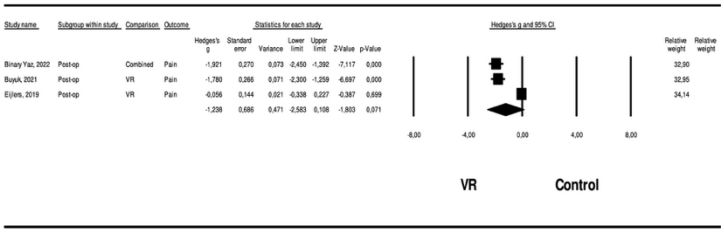
Virtual Reality in Pediatric Surgery

This is a systematic review and meta-analysis examining virtual reality across preoperative, intraoperative, and postoperative pediatric surgical care. The study is directly relevant to Mirawell Health's perioperative deployment pathway (Taylan et al., 2025).

Key Findings

- VR significantly reduced preoperative anxiety, with P < .001.VR significantly reduced intraoperative anxiety, with P = .002.
- The pooled effect on postoperative pain was not statistically significant, with P = .071.
- The pooled effect on postoperative delirium was not statistically significant, with P = .307.
- Heterogeneity and methodological differences across the included studies limited the certainty of the findings.
- The authors recommended additional randomized controlled trials to strengthen the evidence.

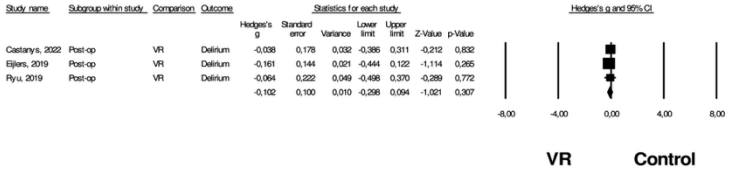
a) Pain



Meta Analysis

Heterogenety: Qvalue=56,920; df=2; I2=96,486 %; Tau^2=1,359;
Test for overal effects: Z=-6,224; p=0.071
Kendall's tau without continuity correction p=0,11719; Kendall's tau continuity correction p=0,29627; Egger's p=0,01785

b) Delirium



Heterogenety: Qvalue=0,326; df=2; I^2=0,000 %; Tau^2=0,000
Test for overal effects: Z=-1,021; p=0.307
Kendall's tau without continuity correction p=0,60151; Kendall's tau continuity correction p=1,000; Egger's p=0,45242

a Forest plot of the effect of VR on post-operative pain. b Forest plot of the effect of VR on post-operative process

The findings support preoperative and intraoperative anxiety as important primary outcomes for perioperative Mirawell Health studies. Postoperative pain, delirium, recovery, opioid consumption, and length of stay should be evaluated separately because the current external evidence does not establish significant improvements in these outcomes.

Extended Validation

Trends in Pediatric Pain Thinking Beyond Opioids

In this review, Walter et al., 2020 discussed emerging opioid-sparing strategies for pediatric pain management, including novel regional anesthesia techniques, block adjuvants, nonopioid medications, enhanced recovery after surgery (ERAS) protocols, and virtual reality (VR). The authors emphasize that pediatric pain care is moving beyond opioids toward multimodal analgesia, with VR showing particular promise as a nonpharmacologic tool for acute procedural and postoperative pain.

Key Findings

- New regional techniques are expanding pediatric postoperative pain management, including QL, ESP, suprainguinal FI, adductor canal, and IPACK blocks, alongside block adjuvants, nonopioid analgesics, and emerging ERAS protocols, although pediatric evidence remains limited for several newer approaches.
- **Virtual reality (VR)** reduces acute procedural pain and anxiety in children, with high patient satisfaction; VR may be more effective in patients with higher baseline pain (≥7/10 on numerical rating scale).

This review outlines opioid-sparing pediatric pain strategies—regional blocks, adjuvants, nonopioid medications, ERAS protocols, and virtual reality—and highlights VR as a promising nonpharmacologic tool for acute and procedural pain.

There is a growing role of nonpharmacologic, opioid-sparing strategies such as VR in pediatric pain management. Mirawell Health Health's focus on accessible, evidence-based immersive pain solutions aligns with this direction and can help translate these advances into bedside care for children and families.

Extended validation summary:

- *Consistent evidence demonstrates feasibility, safety, high engagement, and strong patient acceptance of VR-based pain and anxiety interventions.*
- *Biofeedback-enhanced VR shows potential advantages beyond distraction alone by promoting physiologic self-regulation and skill development.*
- *Current evidence supports continued clinical validation of Mirawell Health as a scalable, non-pharmacologic, opioid-sparing pediatric supportive-care platform.*

Summary of Clinical Evidence

Study (Author, Year)	Design / Population	Intervention / Focus	Key Findings
Olbrecht et al., 2021	Pilot observational; 51 children/adolescents (7–21 y) with postoperative pain	Single 10-min guided relaxation-based VR (Mindful Aurora)	Pain intensity ↓ immediately ($p<0.001$) and at 30 min ($p=0.04$); pain unpleasantness ↓ at all time points ($p<0.001$); anxiety ↓ immediately and at 15 min, but not at 30 min; higher CASI → greater pain reductions; 96% would recommend; no side effects
Orgil et al., 2023	Prospective dataset; 23 adolescents (12–18 y) undergoing surgery	Perioperative VR-BF (Meta Quest 2; Mindfulness Aurora; HeartMath)	91% completed sessions; median 9 sessions; 95% achieved target HRV overall; ~10-min sessions and ~4–5 sessions optimize target achievement; high acceptability
Heydinger et al., 2023	Review	Regional anesthesia and VR for pediatric pain	Regional blocks (QL, ESP, spinal, epidural) effective and opioid-sparing; VR emerging; VR-GR and VR-BF promising but need larger RCTs
Walter et al., 2020	Review	Opioid-sparing pediatric pain: regional, adjuvants, nonopioids, ERAS, VR	New blocks/adjuvants and nonopioid meds support multimodal analgesia; pediatric ERAS data limited but favorable; VR reduces acute procedural pain, high satisfaction, more effective at higher baseline pain
Olbrecht et al., 2021	Pilot; 50 children (7–21 y) with postoperative pain	Single distraction-based VR session (Starlight Xperience)	Pain intensity ↓ immediately ($p<0.0001$) and at 15 min ($p=0.02$); pain unpleasantness ↓ up to 30 min; anxiety ↓ immediately and at 15 min; PCS-C/CASI did not influence response; 94% would recommend; no adverse effects

Summary of Clinical Evidence

Study (Author, Year)	Design / Population	Intervention / Focus	Key Findings
Cheng et al., 2022	Systematic review and meta-analysis of 6 randomized controlled trials involving 379 children with cancer.	VR significantly reduced pain and anxiety compared with control conditions. Pain and anxiety analyses showed high heterogeneity, indicating variation across interventions and study methods.	Provides the most direct independent support for Mirawell Health's pediatric oncology use case, particularly during recurring painful and anxiety-provoking procedures.
Taylan et al., 2025	Systematic review and meta-analysis of studies involving pediatric surgical patients across preoperative, intraoperative, and postoperative settings.	VR significantly reduced preoperative and intraoperative anxiety. Effects on postoperative pain and delirium were not statistically significant.	Supports perioperative anxiety as an important initial clinical endpoint for Mirawell Health. Postoperative pain, delirium, recovery, and opioid use should be evaluated separately.
Eijlers et al., 2019	Systematic review and meta-analysis of 17 studies involving patients aged 21 years or younger. Settings included venous access, oncology, burn care, dentistry, and surgical preparation.	VR significantly reduced patient-reported pain and anxiety. Caregiver- and clinician-reported pain outcomes also favored VR. Most studies evaluated distraction-based VR.	Supports expansion of Mirawell Health across multiple pediatric procedural settings. The evidence validates immersive VR broadly but does not establish the added effect of physiological biofeedback.
Fisher et al., 2014	Systematic review and meta-analysis of 35 studies involving children younger than 18 years with headache, abdominal, musculoskeletal, or neuropathic pain.	Psychological therapies reduced pain symptoms and disability after treatment. Higher treatment doses produced greater pain reduction for headache, but no consistent dose effect was identified for other conditions.	Provides adjacent behavioral validation for Mirawell Health's guided breathing and self-regulation approach. Future studies should measure disability and pain interference in addition to pain intensity.

Summary of Clinical Evidence

Study (Author, Year)	Design / Population	Intervention / Focus	Key Findings
Fournié et al., 2021	Systematic review of **29 studies involving 1,127 adults with chronic diseases**. The evidence included **14 randomized controlled trials**, seven uncontrolled studies, and additional pilot, feasibility, and experimental studies.	Heart rate variability biofeedback delivered as the main intervention or as an adjunct to standard care. Most protocols used approximately **six breaths per minute**, typically through **4–12 supervised sessions** with home practice.	HRV biofeedback was generally feasible, with no serious intervention-related adverse effects reported. Positive findings were reported across anxiety, depression, sleep, cognitive performance, pain, cardiovascular measures, and quality of life, although results varied by condition. Of 15 studies evaluating depression, 12 reported significant improvements; of 12 examining stress or anxiety, nine reported significant improvements.
Zaccaro et al., 2018	Systematic review of 15 studies selected from 2,461 abstracts. Participants were healthy adults aged 18–65 years. Ten studies used within-subject designs and five used pre-post designs; no included study used a randomized controlled or longitudinal design.	Voluntary slow-breathing techniques performed at fewer than 10 breaths per minute, including paced breathing, HRV biofeedback, Zen Tanden breathing, and Prana-Yoga breathing. Five included studies examined HRV biofeedback.	Slow breathing was associated with increased HRV and respiratory sinus arrhythmia, along with changes in central nervous system activity. Reported psychological outcomes included greater relaxation, comfort, pleasantness, positive energy, and alertness, as well as lower arousal, anxiety, depression, anger, and confusion. Breathing near six breaths per minute was frequently associated with increased HRV-related measures and favorable psychological outcomes. Methodological heterogeneity limited certainty.

Economic Value Analysis

Commercial Market Forecasts

The seven major chronic pain markets (United States, EU5, and Japan) were valued at approximately US$21.2 billion in 2023 and are projected to reach approximately US$28.9 billion by 2034 (IMARC Group, 2024).

Commercial analyses identify several major growth drivers, including:

- Increasing prevalence of chronic pain disorders.
- Demand for non-opioid treatment strategies.
- Growing adoption of personalized healthcare.
- Expansion of digital-health technologies.
- Increased use of remote monitoring and wearable devices.

These market trends suggest increasing receptiveness among healthcare providers and patients towards digital therapeutics, behavioral interventions, biofeedback technologies, and remote care platforms.

Chronic pain market size (2023):

US$21.2 billion.

Projected market size (2034):

US$28.9 billion.

Major growth drivers include:

- Expansion of non-opioid treatment approaches.
- Adoption of digital-health technologies.
- Increased use of wearable monitoring devices.
- Growth in personalized pain-management strategies.
- Rising prevalence of chronic disease and chronic pain

Beachhead Market: Pediatric Oncology

Mirawell Health's initial commercial focus is pediatric oncology. Internal market analysis estimates approximately 15,000-16,000 new pediatric oncology patients annually in the U.S. market.

The U.S. pediatric oncology population experiences frequent procedural pain, anxiety, and repeated treatment encounters, making it well suited for longitudinal use of Mirawell Health. Approximately 15,780 children are diagnosed with cancer annually in the United States.

Metric	Estimate
SOM	$300M
SAM	$3B-$5B
TAM	$20B+

Source: Mirawell Health

Economic Value Analysis

Market Opportunity Analysis

Pediatric surgery represents a large and underserved market for non-pharmacologic pain management solutions. Approximately 3.9 million pediatric surgical procedures are performed annually in the United States, with nearly 4.7% of children undergoing surgery each year (Rabbitts & Groenewald, 2020).

Despite advances in surgical care, perioperative pain management remains heavily dependent on opioids, creating clinical, economic, and operational burdens for healthcare systems.

Mirawell Health's biofeedback-enabled VR platform directly addresses these challenges by providing a scalable, opioid-sparing approach to pain and anxiety management.

Metric	Value
Annual pediatric surgeries in the U.S.	3.9 million
Children undergoing surgery annually	3.1 million
Children receiving surgery annually	4.7%
Inpatient pediatric surgeries analyzed nationally	323,258
Hospitals performing pediatric surgery	2,857
Median pediatric inpatient surgery volume per hospital	8 cases/year
Children's hospitals in the U.S.	>200
Large pediatric hospitals identified	30+
Pediatric oncology diagnoses annually	~15,780
Pediatric burn injuries annually	~250,000

$11.8B

annual U.S. healthcare burden associated with pediatric pain-related conditions.

$19.5B

annual societal burden associated with adolescent chronic pain in the United States.

(Rabbitts & Groenewald, 2020; Berry et al., 2021)

Economic Value Analysis

Economic Burden

Post-Operative Opioid Utilization

- Surgery remains one of the leading drivers of opioid prescribing in pediatric populations (Chua et al., 2024).
- A 2024 U.S. study found that **71% of adolescents had unused opioid tablets after surgery**, highlighting substantial overprescribing and diversion risk (Odegard et al., 2024).
- The American Academy of Pediatrics recommends multimodal, opioid-sparing approaches and advises against opioid-only pain management strategies (Hadland et al., 2024).

Persistent Opioid Use

- Approximately **4.8% of opioid-naïve adolescents developed persistent opioid use after surgery** (Harbaugh et al., 2018).
- A recent U.S. analysis reported that **3% of youth continued filling opioid prescriptions 3-6 months after surgery**, indicating ongoing dependence risk (Sutherland et al., 2024).
- Persistent opioid use has been linked to chronic pain, substance use disorders, and increased long-term healthcare utilization (Harbaugh et al., 2018).

Procedural Anxiety

- Pain and anxiety frequently coexist during pediatric procedures and recovery.
- Preoperative anxiety has been identified as a significant predictor of moderate-to-severe postoperative pain, increasing analgesic requirements and recovery burden (Rede et al., 2024).
- In a prospective U.S. adolescent surgery cohort, **37.4% of patients reported anxiety symptoms before surgery** (Sutherland et al., 2025).

Nursing Burden

- Opioid-based care pathways require medication administration, adverse-event monitoring, patient education, and follow-up.
- Children's hospitals implementing opioid stewardship programs achieved significant reductions in opioids prescribed and consumed while maintaining pain control (Hadland et al., 2024).
- Hospitals continue to seek workflow-friendly, non-pharmacologic interventions that integrate into existing nursing and child-life workflows.

3.9 million
pediatric surgeries performed annually in the United States.

4.8%
persistent opioid use among opioid-naïve adolescents following surgery.

3%
continue opioid prescriptions 3-6 months after surgery.

71%
of adolescents report unused opioids after surgery.

37.4%
report preoperative anxiety symptoms.

>200
children's hospitals represent concentrated pediatric surgical care settings.

Economic Value Analysis

Economic Burden

Length of Stay

- Poorly controlled pain and anxiety contribute to delayed recovery and increased healthcare resource utilization.
- Children with greater medical complexity require additional perioperative resources and specialized care services (Berry et al., 2021).
- Enhanced Recovery After Surgery (ERAS) programs increasingly emphasize multimodal pain management to improve recovery trajectories.

Pain-Related Complications

- Moderate-to-severe postoperative pain affected 36.6% of pediatric patients at 12 hours following surgery, and preoperative anxiety was associated with increased postoperative pain severity (Rede et al., 2024).
- Chronic pain, anxiety, sleep disturbances, and reduced quality of life may persist beyond the immediate postoperative period (Sutherland et al., 2025).
- Pain-related complications are associated with increased healthcare utilization, reduced patient satisfaction, and poorer recovery outcomes.

Competitive Positioning

Compared with conventional VR-based pain interventions, Mirawell Health differentiates itself through:

Capability	Conventional VR	Mirawell Health
VR Distraction	Yes	Yes
Biofeedback Integration	Limited	Yes
Physiological Sensing	Limited	Yes
Real-Time Adaptation	Limited	Yes
Clinical Dashboard	Limited	Yes
RTM Reimbursement Potential	Limited	Yes
Longitudinal Monitoring	Limited	Yes

Current pediatric surgical care continues to be challenged by opioid exposure, persistent opioid use, procedural anxiety, staffing burden, and recovery inefficiencies. Recent U.S. evidence demonstrates substantial opioid overprescribing, ongoing risks of long-term opioid use, and high rates of anxiety and postoperative pain among pediatric patients.

Mirawell Health's real-time biofeedback and adaptive VR platform directly addresses these challenges by providing an objective, scalable, and non-pharmacologic approach to pain and anxiety management, supporting opioid-sparing care pathways, improved workflow efficiency, and enhanced recovery outcomes

Source: Mirawell Health

Mirawell Health: Evidence, Deployment & Scale

Pediatric surgery represents a natural expansion opportunity for Mirawell Health, leveraging its existing evidence base in post-operative pain management and supporting hospitals' growing focus on opioid reduction, enhanced recovery, and improved patient experience.

Expansion Market: Pediatric Surgery

Category	Details
Market Need	• Post-operative pain remains a significant challenge across pediatric health systems. • Opioids continue to be widely used despite increasing adoption of multimodal pain management strategies. • Hospitals are actively seeking non-pharmacologic interventions that improve recovery while reducing opioid exposure.
Target Segments	• Orthopedic Surgery • General Surgery • Colorectal Surgery • Cardiac Surgery • Ambulatory Surgery Centers
Strategic Value for Mirawell Health	• Builds on existing clinical evidence in pediatric pain management. • Supports hospital opioid stewardship initiatives. • Integrates into existing perioperative workflows. • Enables repeated use throughout the surgical care continuum.

Large unmet need in pediatric post-operative pain management.

Growing adoption of non-opioid and multimodal pain management approaches.

Applicable across orthopedic, general, colorectal, and cardiac surgery, as well as ambulatory surgery centers.

Existing pediatric pain and anxiety evidence supports expansion into broader surgical settings.

Mirawell Health: Evidence, Deployment & Scale

Expansion Market: Pediatric Chronic Pain

Category	Details
Market Opportunity	• Global chronic pain market valued at approximately $21.2B in 2023 and projected to reach $28.9B by 2034. • Non-opioid therapies represent one of the fastest-growing segments in pain management. • Growth is driven by increasing adoption of digital therapeutics, wearable technologies, and personalized care models.
Key Market Drivers	• Approximately 20.5% of U.S. adults live with chronic pain. • The United States represents the largest chronic pain treatment market globally. • Healthcare systems are actively shifting toward non-opioid treatment pathways. • Adoption of biofeedback and digital health solutions continues to increase.
Target Conditions	• Chronic Low Back Pain • Fibromyalgia • Migraine Disorders • Musculoskeletal Pain • Neuropathic Pain Conditions
Strategic Value for Mirawell Health	• Biofeedback has demonstrated effectiveness across multiple chronic pain conditions. • Adaptive VR may improve patient engagement and treatment adherence. • RTM reimbursement pathways create recurring revenue opportunities. • Provides a scalable expansion pathway into adult chronic pain and rehabilitation markets.

Global chronic pain market valued at **~$21.2B** in 2023 and projected to reach **$28.9B** by 2034.

~20.5% of U.S. adults experience chronic pain.

US represents the largest chronic pain treatment market globally.

Key target conditions include Chronic Low Back Pain, Fibromyalgia, Migraine Disorders, Musculoskeletal Pain, and Neuropathic Pain.

Strong market movement toward **non-opioid therapies and digital therapeutics.**

Mirawell Health: Evidence, Deployment & Scale

Expansion Market: Burn Care

Category	Details
Market Need	• Approximately 250,000 pediatric burn injuries occur annually in the United States. • Burn dressing changes are frequently reported as equally or more painful than the initial injury. • Anticipatory anxiety often amplifies procedural pain and distress.
Clinical Validation	• Multiple studies demonstrate that VR can reduce pain and anxiety during burn-care procedures. • Evidence supports use during dressing changes, rehabilitation, and recovery. • Therapeutic VR is among the most established digital interventions in pediatric burn care.
Strategic Value for Mirawell Health	• Combines immersive VR with real-time biofeedback to address both pain and anxiety. • Supports repeated use across multiple dressing changes and recovery visits. • Provides differentiation compared with VR-only solutions. • Creates a high-value specialty care entry point for pediatric hospitals.

Mirawell Health's expansion strategy targets three high-value pediatric care markets where pain, anxiety, and opioid dependence remain major clinical and operational challenges.

Together, Pediatric Surgery, Pediatric Chronic Pain, and Burn Care represent large and growing opportunities that align closely with Mirawell Health's core strengths in biofeedback, adaptive VR, and non-pharmacologic pain management.

~250,000

pediatric burn injuries occur annually in the United States.

Burn dressing changes are often reported as equally or more painful than the original injury.

Multiple studies support VR's ability to reduce procedural pain and anxiety.

Therapeutic VR is one of the most established digital interventions in pediatric burn care.

Opportunity for repeated use across dressing changes, rehabilitation, and recovery.

Mirawell Health: Evidence, Deployment & Scale

Market Opportunity & Deployment Summary

Beachhead market: Pediatric oncology supportive care.	Primary use cases: Procedural anxiety, perioperative pain, recovery support, and self-regulation training.	Pediatric surgery represents the most immediate expansion opportunity
Pediatric chronic pain is a high-value long-term market.	Burn care and rehabilitation provide additional future growth pathways.	Hospital-based deployment model validated through clinical studies and pilot testing.
Home-use capability demonstrated by continued post-discharge use among participants.	Strong patient engagement supports longitudinal use and repeat utilization.	Closed-loop biofeedback platform differentiates Mirawell Health from passive VR distraction solutions.
Real-time HRV and respiratory monitoring enable objective physiologic feedback.	Non-pharmacologic and opioid-sparing positioning aligns with current healthcare priorities.	Scalable across multiple pediatric care settings including oncology, surgery, supportive care, and rehabilitation.
Future clinician-facing insights may support broader workflow integration and outcome monitoring.	Multiple commercialization pathways including hospital deployment, specialty programs, and future home-based supportive care.	

Mirawell Health sits at the convergence of five rapidly expanding markets: pediatric oncology supportive care, digital therapeutics, virtual reality therapeutics, biofeedback technology, and non-opioid pain management. By reducing pain, anxiety, opioid utilization, and operational burden while enabling recurring reimbursement through RTM pathways, Mirawell Health offers health systems both clinical and economic value. Its beachhead strategy in pediatric oncology provides a clinically validated entry point into a broader platform opportunity spanning pediatric surgery, chronic pain, women's health, rehabilitation, infusion services, and home-based care, creating a scalable pathway toward a multi-billion-dollar market opportunity

User Testimonials

"IslandVR makes the mind-body connection visible. By combining breathing biofeedback with an immersive experience, it can help children better understand how their bodies respond to pain and develop self-regulation skills that extend beyond the clinical setting."

Sara Williams, PhD
Pediatric Pain Psychologist; Co-Founder and Clinical Professor of Anesthesiology, Perioperative and Pain Medicine, Stanford University

"Immersive technologies become truly impactful when they produce measurable clinical outcomes. Demonstrating meaningful improvements in pain management and recovery would create a compelling case for adoption."

Todd A. Ponsky, MD
Director, Clinical Growth and Transformation; Pediatric Surgeon, Cincinnati Children's Hospital

"When children can see how breathing and heart-rate regulation influence their experience, biofeedback becomes more meaningful and empowering. IslandVR has the potential to help young patients build confidence in their ability to manage stress and discomfort."

Nicole Zakha, PhD
Pediatric Psychologist, Cincinnati Children's Hospital Medical Center

"Healthcare organizations are actively seeking innovative approaches that improve patient experience without adding operational complexity. Technologies that demonstrate value for both patients and health systems will stand out."

Derek Wheeler, MD, MMM, MBA
Executive Vice President and Chief Operating Officer, Ann & Robert H. Lurie Children's Hospital of Chicago

"Any intervention that helps reduce reliance on sedatives or opioids deserves serious consideration. IslandVR offers a promising way to prepare patients for pain management while supporting recovery through engagement and education."

Katherine Deans, MD, MHSc
Surgeon-in-Chief, Nemours Children's Health, Delaware Valley

"Introducing IslandVR before surgery could help children build practical coping skills for managing pain and anxiety. Its mind-body approach aligns well with modern prehabilitation and recovery programs."

Victor Garcia, MD, FACS, FAAP
Founding Director, Trauma Services; Professor of Surgery, Cincinnati Children's Hospital Medical Center

User Testimonials

"Breathing and relaxation techniques are highly valuable, but maintaining patient engagement is often challenging. IslandVR could help reinforce these coping skills through a more interactive and engaging experience."

Lori Lycans, MSW, LSW
Licensed Social Worker and Therapist, Seacrest Recovery Center

"Many patients understand the value of breathing exercises but struggle to practice them consistently. A guided platform like IslandVR could provide the feedback and motivation needed to build lasting habits."

Taylor Matheson, MSN, PMHNP
Psychiatric Nurse Practitioner, Seacrest Recovery Center and MPP

"Virtual reality has a role in pediatric pain care, but adoption depends on ease of use, affordability, and workflow integration. Solutions that fit naturally into clinical practice are far more likely to succeed."

Joseph Cravero, MD
Joseph Cravero, MD

"Children engage best when they feel involved and empowered. IslandVR has the potential to transform therapeutic exercises into interactive experiences that patients genuinely want to use."

Scott Shaw
Game and Technology Specialist, Child Life, Nemours Children's Hospital

"Pain management extends beyond medication alone. A simple, engaging VR experience could offer patients an additional tool to help manage discomfort during treatment."

Richard "Scott" Adams, BSN
Oncology Nurse, Mercy Health

Conclusion

The evidence reviewed in this report demonstrates that Mirawell Health is emerging as a promising non-pharmacologic digital health platform for pediatric pain and anxiety management. Across feasibility studies, pilot randomized trials, independent heuristic evaluation, stakeholder interviews, and Extended Validation studies, the platform consistently demonstrated strong patient engagement, high acceptability, favorable usability, and a strong safety profile.

Mirawell Health's unique integration of real-time physiological monitoring, biofeedback, guided breathing, and immersive virtual reality directly addresses important unmet needs in pediatric supportive care, particularly the need for scalable alternatives to medication-based symptom management. Early evidence suggests that biofeedback-guided VR may support reductions in pain, anxiety, and treatment-related distress while fostering self-regulation skills that can extend beyond the VR experience itself.

Although further large-scale efficacy trials are warranted, the current body of evidence supports the feasibility, acceptability, and clinical potential of Mirawell Health across pediatric oncology, perioperative care, procedural anxiety management, and future expansion areas including chronic pain and supportive care.

Collectively, these findings position Mirawell Health as a differentiated pediatric digital therapeutic platform with substantial opportunities for clinical adoption, evidence generation, and long-term scale. Together with the protocol-development and Extended Validation findings, these results justify progression to adequately powered trials evaluating efficacy, opioid use, durability of benefit, physiological performance, and implementation outcomes across pediatric care settings.

Beyond its immediate application in pediatric oncology and perioperative care, Mirawell Health represents a broader shift toward personalized, non-pharmacologic supportive care. The platform combines physiological sensing, biofeedback, immersive virtual reality, and behavioral skill development within a single intervention, allowing patients to actively participate in managing pain, anxiety, and stress. Unlike traditional distraction-based approaches, Mirawell Health is designed to teach self-regulation skills that may persist beyond individual sessions, creating the potential for sustained clinical benefit across the treatment journey.

Mirawell Health enters the market at a time when healthcare systems are actively seeking opioid-sparing, workflow-friendly, and evidence-based solutions that improve patient experience without increasing operational burden. The combination of encouraging clinical findings, strong stakeholder interest, favorable usability assessments, and a scalable technology architecture positions Mirawell Health as a promising platform for future deployment across pediatric oncology, surgery, chronic pain, rehabilitation, and supportive-care environments. Continued evidence generation will further clarify its role in improving clinical outcomes, patient engagement, and healthcare delivery.

Mirawell Health demonstrates how clinically grounded digital therapeutics can transform supportive care by combining engagement, self-regulation, and physiological feedback within a scalable pediatric platform. The evidence supports continued investment in its clinical validation and future deployment.

- Stan Kachnowski, Chair, HITLAB

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