

Virtually Better

Virtual Reality for Chronic and Acute Pain

Brennan Spiegel MD, MSHS

Cedars-Sinai

Disclosures

- I receive no funding from VR companies
- AppliedVR provides software support for my NIH-funded grants
- I will not be discussing **off-label and/or investigational uses of drugs** or products



Learning objectives

1. Introduce the new field of Medical Extended Reality (MXR)
2. Explore how VR is used to manage acute and chronic pain in the context of the opioid epidemic
3. Evaluate clinical data using VR to support mental health
4. Discuss implementation and funding challenges to scaling MXR across healthcare













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RESEARCH ARTICLE

A Virtual Out-of-Body Experience Reduces Fear of Death

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**VR is a tool that
modifies perception.**

When used to recalibrate unhealthy perceptions, VR becomes a radical new therapy to improve quality of life.

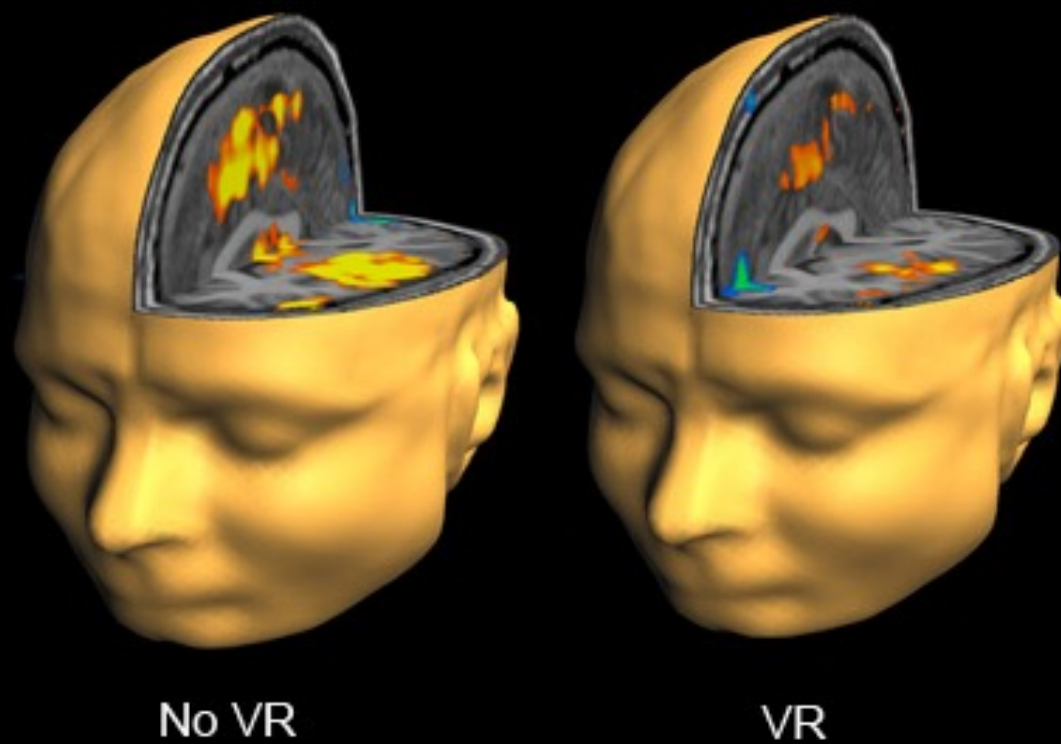


Courtesy of TRIPP VR

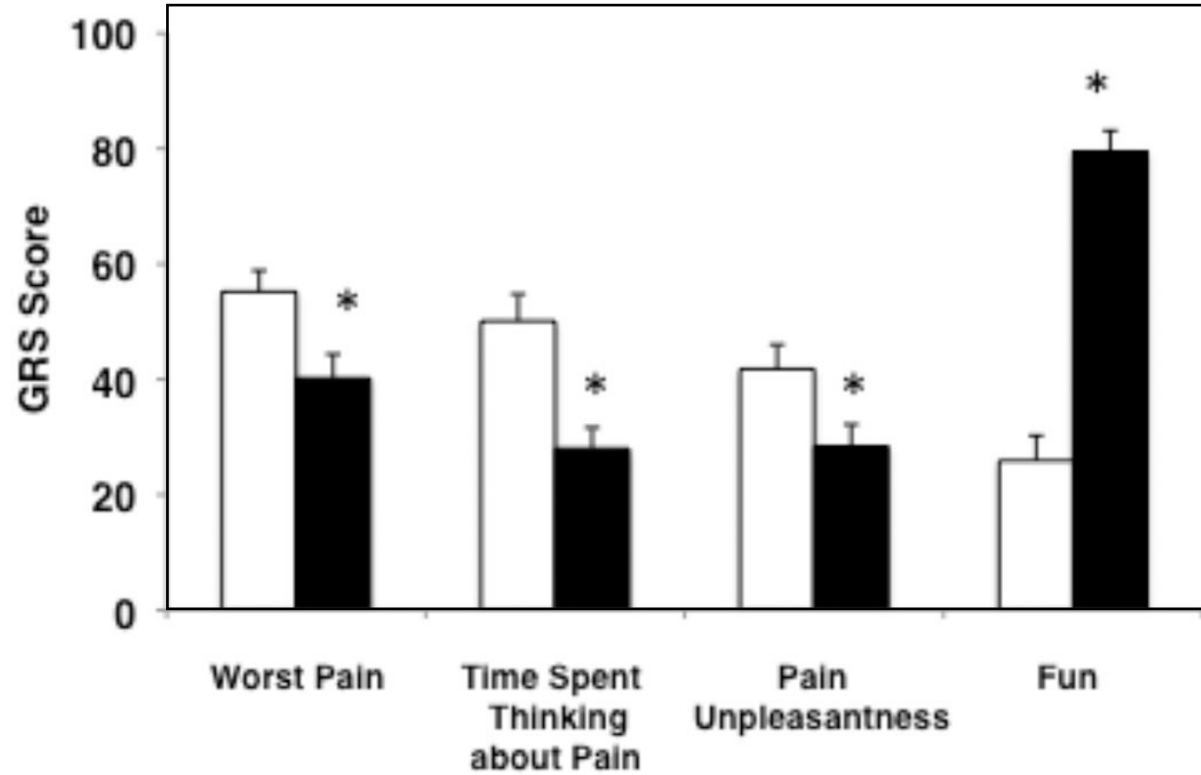


Courtesy of Dolphin Swim Club

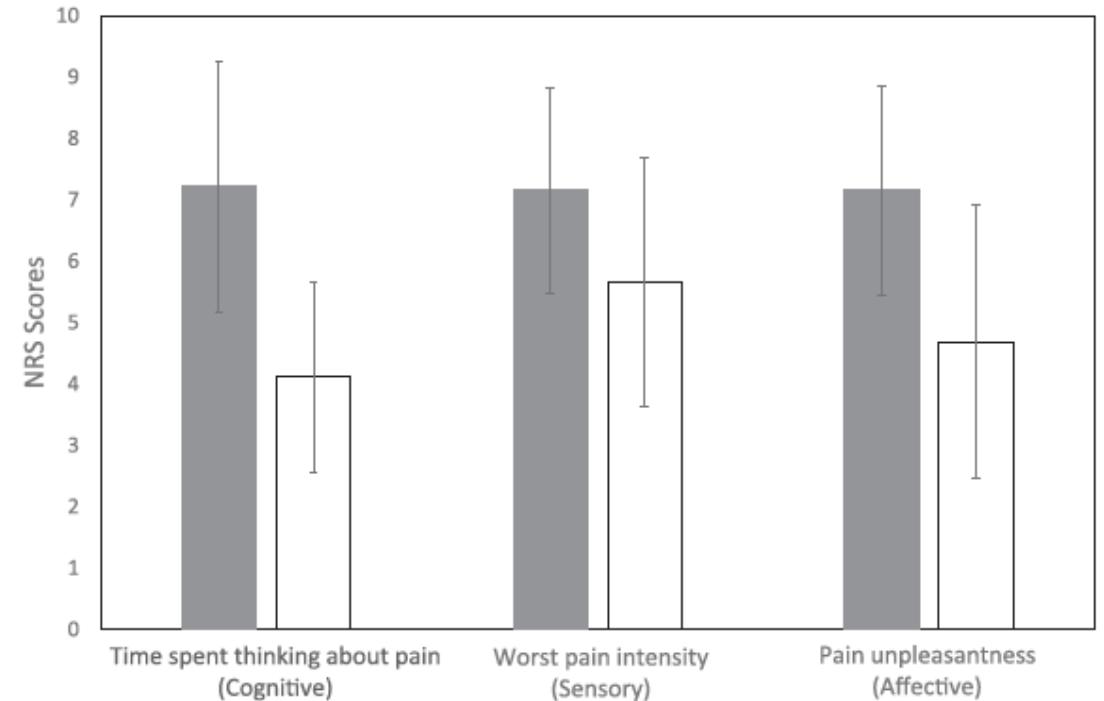
Pain Related Brain Activity is reduced during VR



Burn Dressing Change



Childbirth

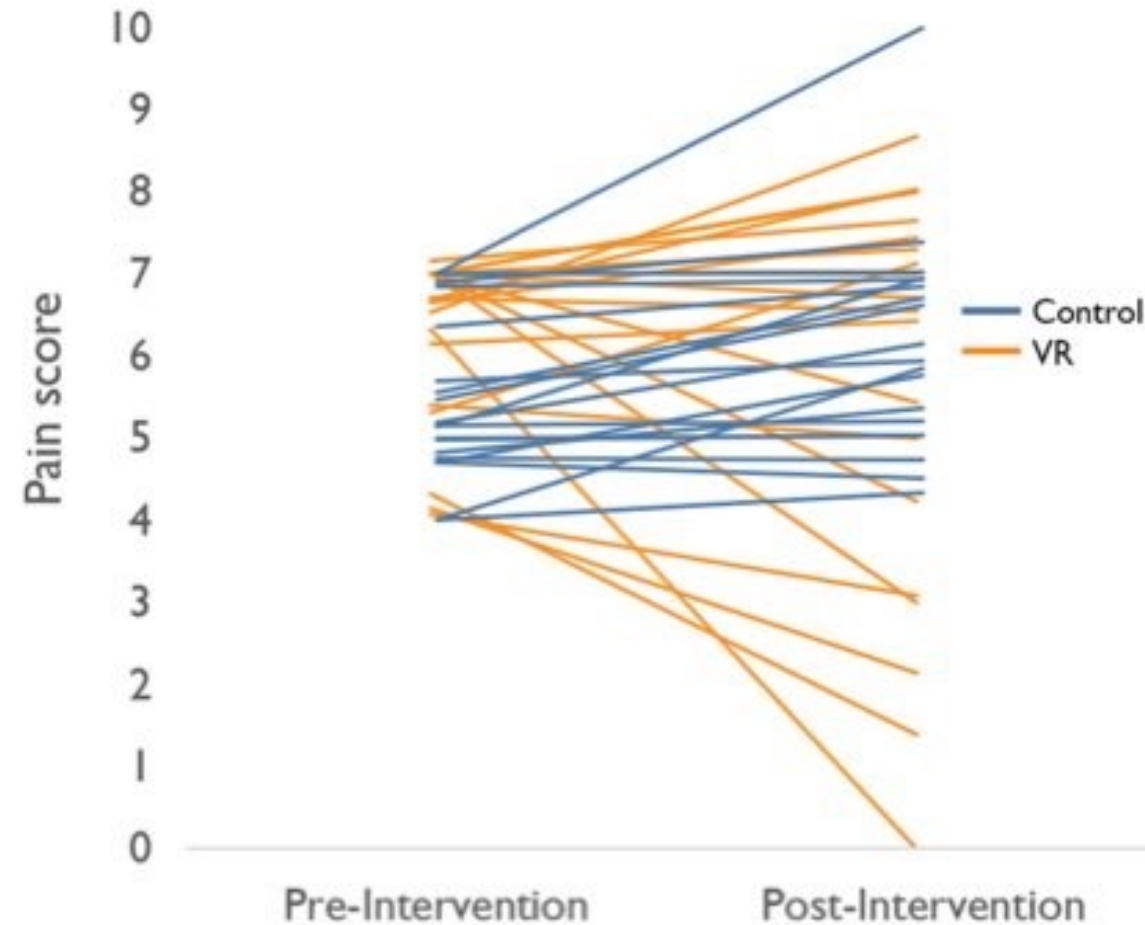


Schmitt YS, et al. *Burns*. 2011;37:61-8
Frey et al. *Anesth Analg* 2018

Virtual Reality Reduces Pain in Laboring Women: A Randomized Controlled Trial

Melissa S. Wong  , Brennan M.R. Spiegel, Kimberly D. Gregory

American Journal of
Perinatology
Maternal-Fetal and Neonatal Medicine



The Analgesic Effects of Opioids and Immersive Virtual Reality Distraction: Evidence from Subjective and Functional Brain Imaging Assessments

Table 1. Subjective Pain/Fun Assessments by Treatment Condition

Outcome variable	VR−/opioid−	VR+/opioid−	VR−/opioid+	VR+/opioid+
Worst pain intensity	8.28 (0.83)	5.94 (2.21)*	7.72 (1.86)	4.50 (1.87)*‡
Pain unpleasantness	8.56 (0.53)	5.33 (2.16)*	7.17 (1.60)†	4.05 (1.98)*‡
Time spent thinking about pain	8.72 (1.25)	4.56 (2.46)*	7.78 (1.79)	3.78 (1.72)*‡
Fun	0.56 (1.33)	6.56 (2.19)*	0.33 (0.50)	6.17 (3.04)*‡

Mean (sd) ratings for the primary (worst pain intensity) and secondary (pain unpleasantness, time spent thinking about pain, and amount of fun during the procedure) outcome measures for participants in each treatment condition ($n = 9$), including results of univariate ANOVA analyses.

VR = virtual reality distraction.

† $P < 0.05$ indicates difference between treatment group and control (VR−/opioid−) group.

* $P < 0.01$ indicates difference between treatment group and control (VR−/opioid−) group.

‡ $P < 0.01$ indicates difference between combined treatment (VR+/opioid+) group and opioid alone (VR−/opioid+) group.

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Can Visual Distraction Decrease the Dose of Patient-Controlled Sedation Required During Colonoscopy? A Prospective Randomized Controlled Trial



Figure 1 The Eyetrek system (Olympus, Tokyo, Japan).

Table 3 Summary of results

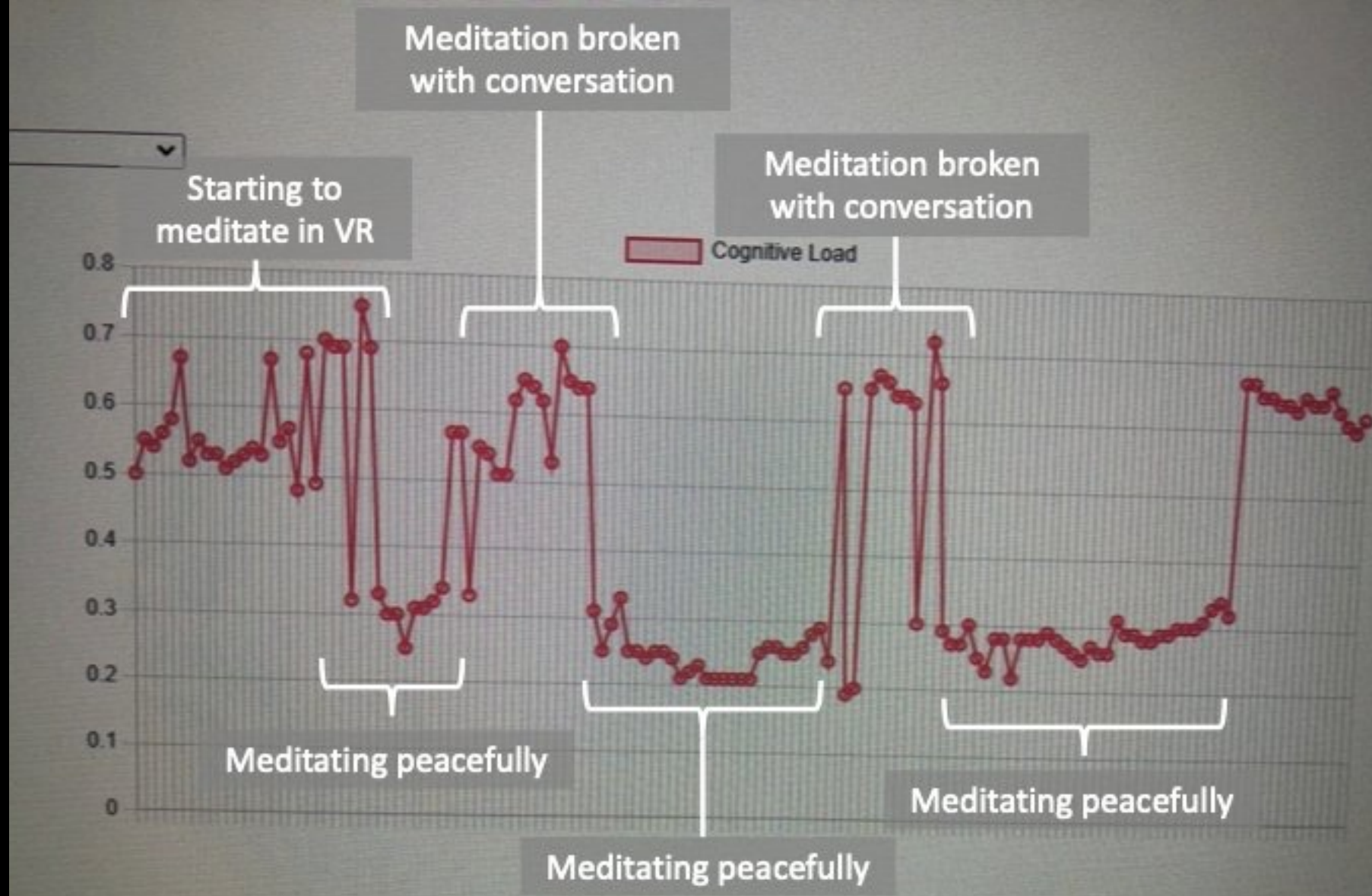
	Group 1 visual distraction + PCS (n = 52)	Group 2 audiovisual distraction + PCS (n = 52)	Group 3 PCS alone (n = 53)	P value
Mean dose of propofol $\pm$ SD, mg/kg	1.17 $\pm$ 0.81	0.81 $\pm$ 0.49	1.18 $\pm$ 0.60	<0.01*
Mean pain score $\pm$ SD (range 0–10)	6.2 $\pm$ 2.2	5.1 $\pm$ 2.5	7.0 $\pm$ 2.4	<0.01* †
Mean satisfaction score $\pm$ SD (range 0–10)	8.2 $\pm$ 2.4	8.4 $\pm$ 2.4	6.1 $\pm$ 2.9	<0.01* †
Willing to repeat procedure with same mode of sedation, n (%)	38 (73%)	44 (85%)	28 (53%)	<0.01#

PCS, patient-controlled sedation; * One-way ANOVA; † Kruskal-Wallis test; # Pearson chi-squared test.



Figure 2 The endoscopy suite set-up for colonoscopy in a patient receiving audiovisual distraction and patient-controlled sedation.

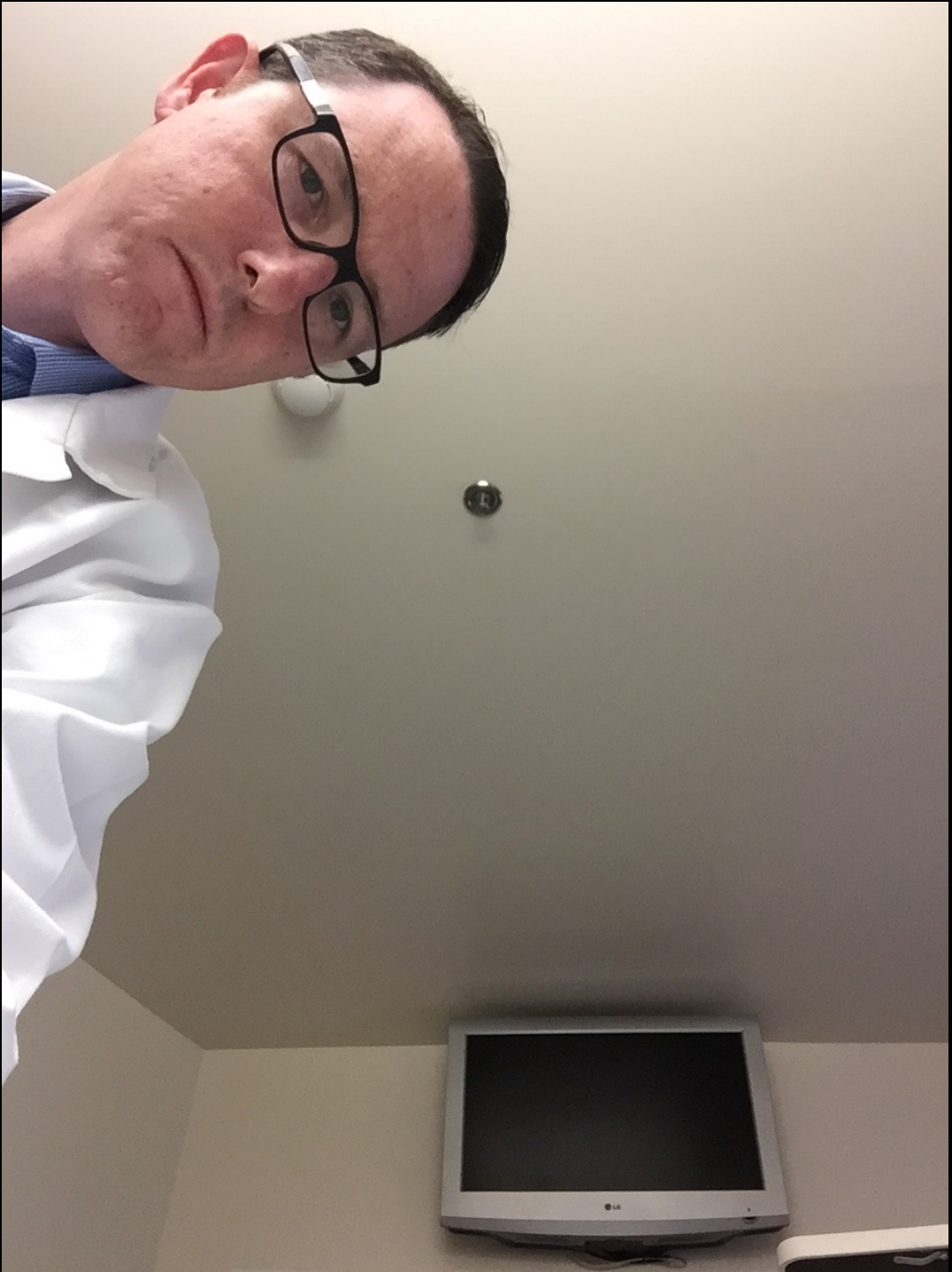




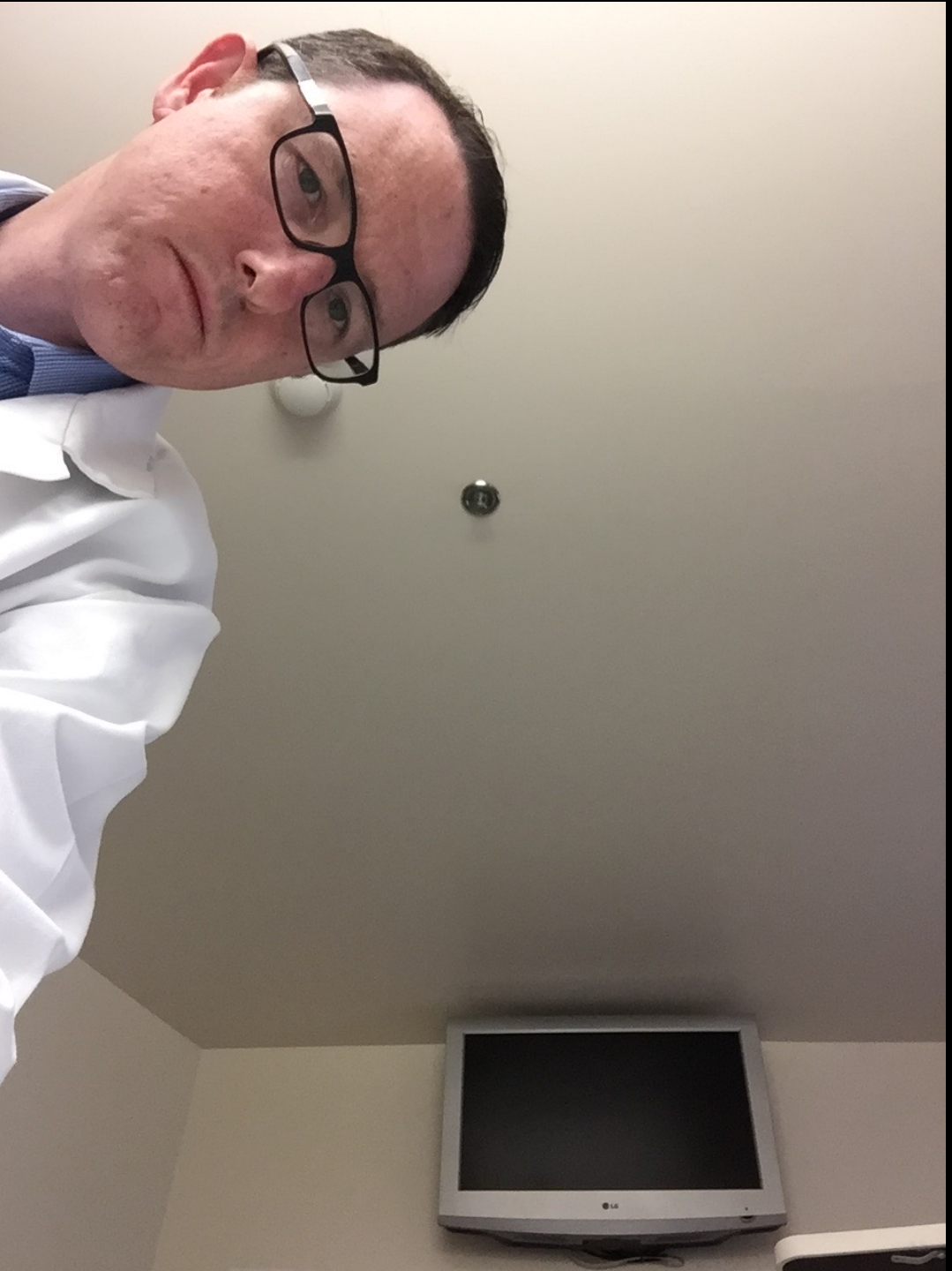














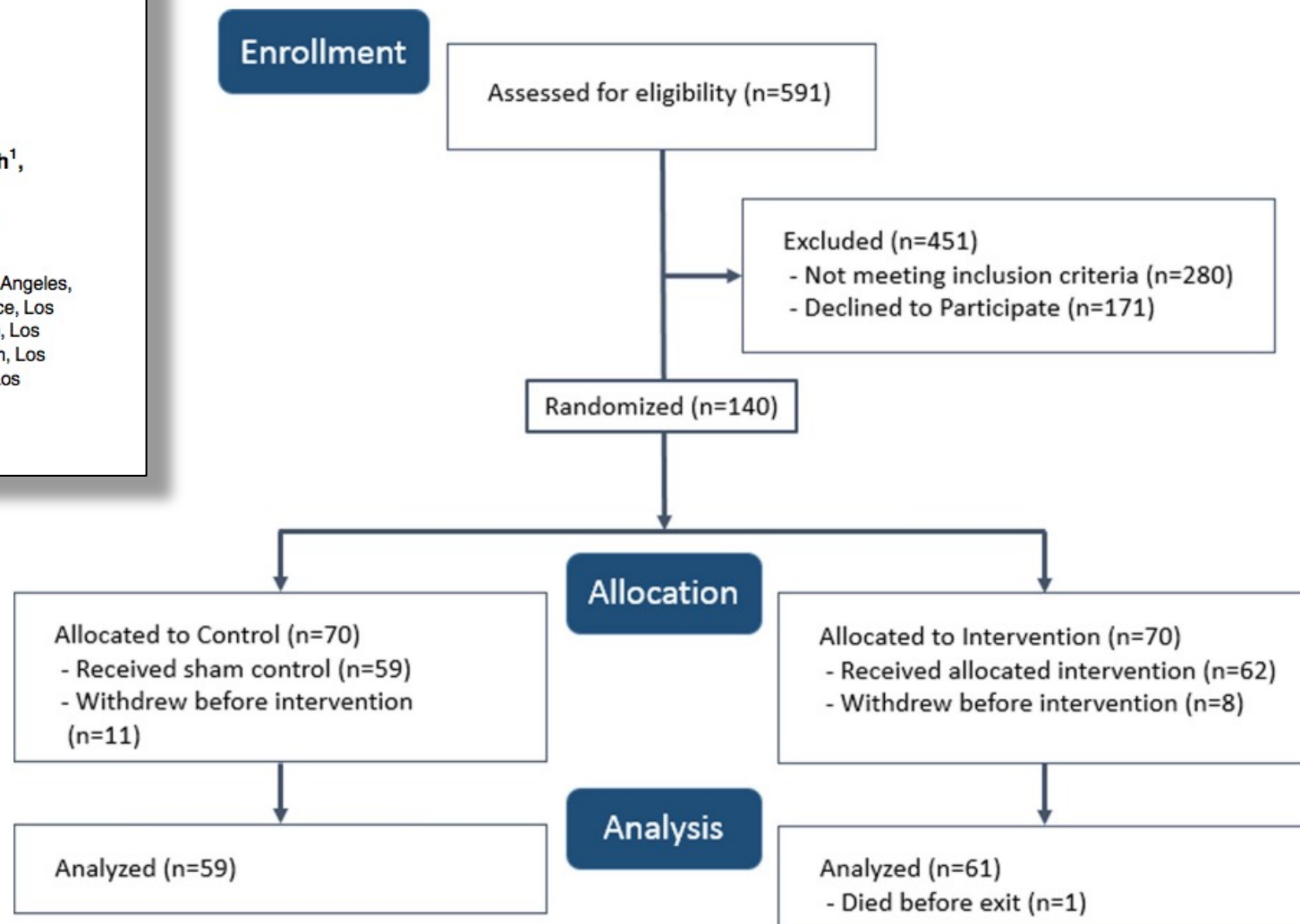


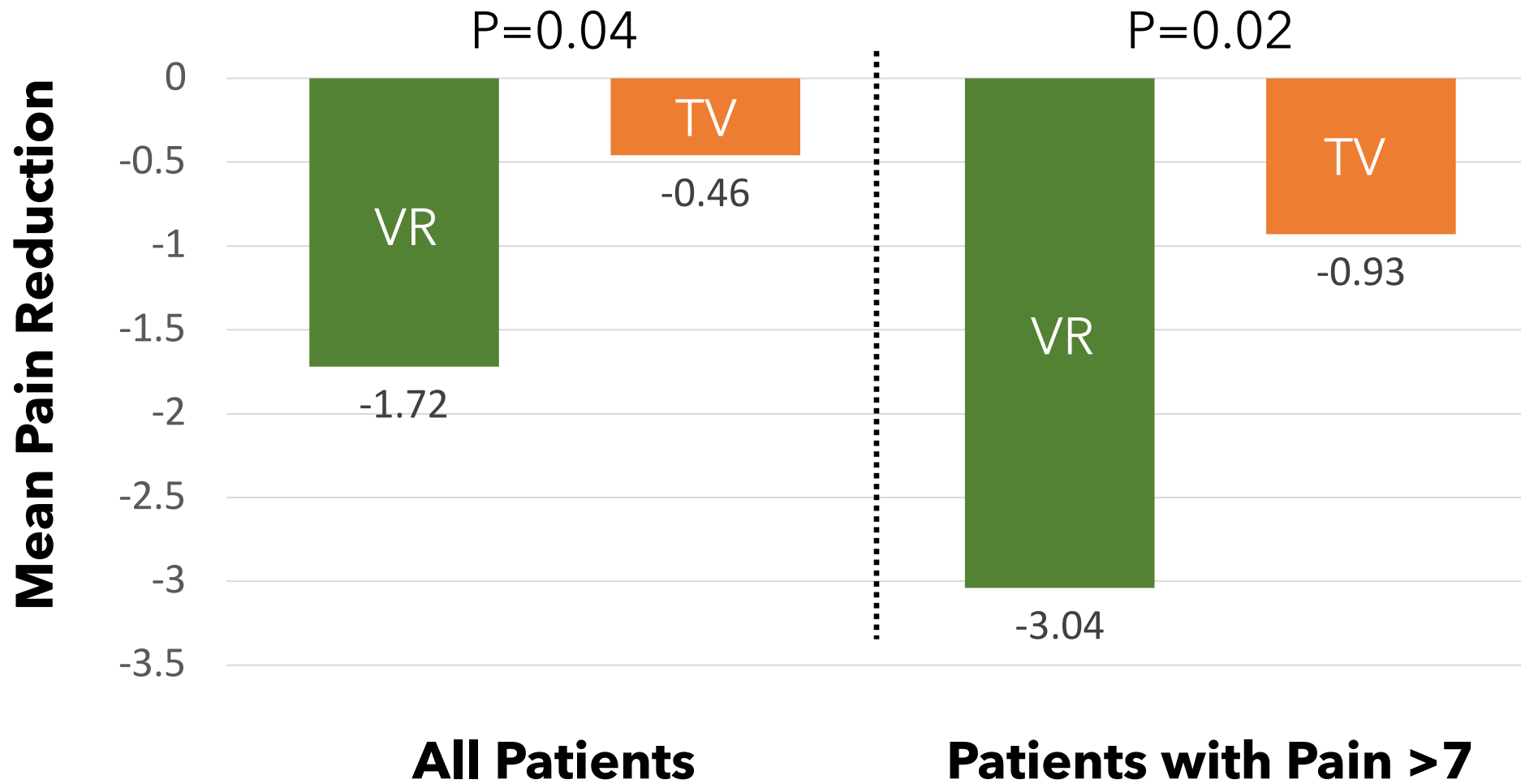
Virtual reality for management of pain in hospitalized patients: A randomized comparative effectiveness trial

Brennan Spiegel^{1,2*}, Garth Fuller¹, Mayra Lopez¹, Taylor Dupuy¹, Benjamin Noah¹, Amber Howard¹, Michael Albert¹, Vartan Tashjian¹, Richard Lam¹, Joseph Ahn¹, Francis Dailey¹, Bradley T. Rosen^{1,3}, Mark Vrahas⁴, Milton Little⁴, John Garlich⁴, Eldin Dzibur¹, Waguih IsHak⁵, Itai Danovitch⁵

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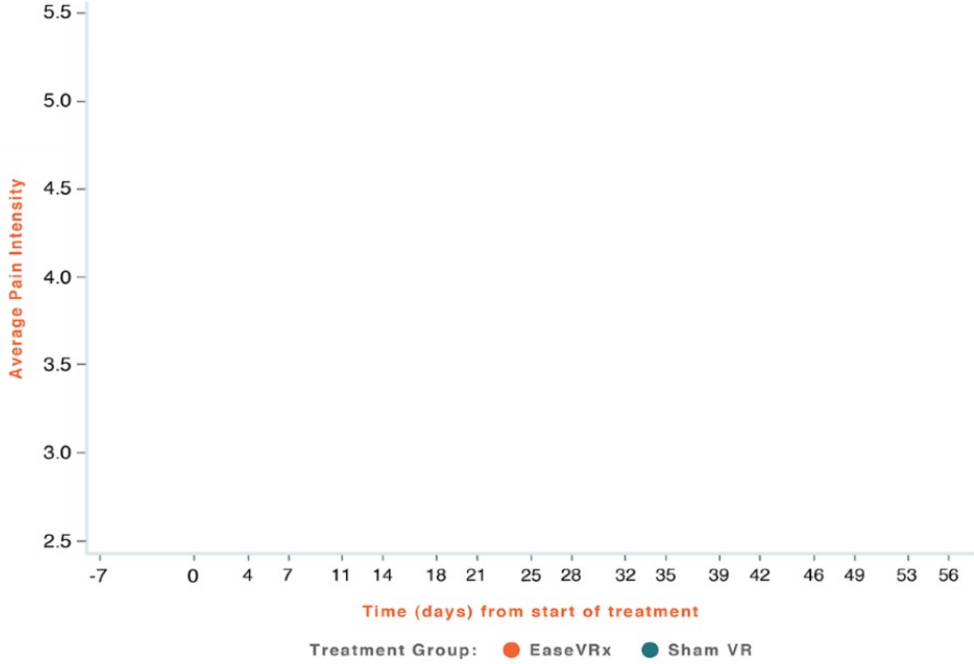
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An 8-Week Self-Administered At-Home Behavioral Skills-Based Virtual Reality Program for Chronic Low Back Pain: Double-Blind, Randomized, Placebo-Controlled Trial Conducted During COVID-19

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FDA NEWS RELEASE

FDA Authorizes Marketing of Virtual Reality System for Chronic Pain Reduction

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For Immediate Release: November 16, 2021

Español

The U.S. Food and Drug Administration today authorized marketing of EaseVRx, a prescription-use immersive virtual reality (VR) system that uses cognitive behavioral therapy and other behavioral methods to help with pain reduction in patients 18 years of age and older with diagnosed chronic lower back pain.

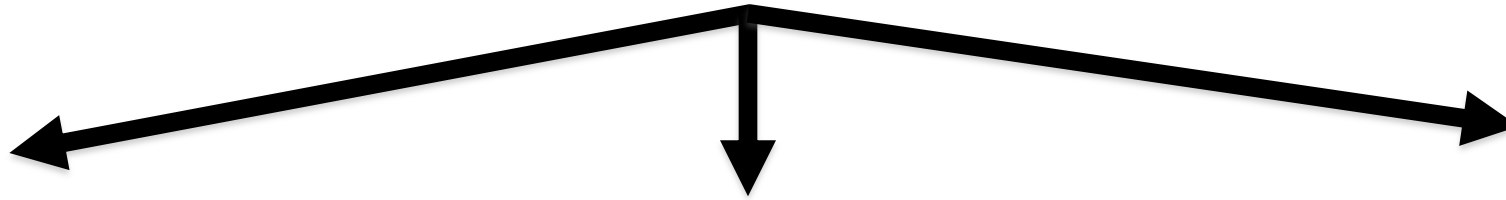
“Millions of adults in the United States are living with chronic lower back pain that can affect multiple aspects of their daily life,” said Christopher M. Loftus, M.D., acting director of the Office of Neurological and Physical Medicine Devices in the FDA’s Center for Devices and Radiological Health. “Pain reduction is a crucial component of living with chronic lower back pain. Today’s authorization offers a treatment option for pain reduction that does not include opioid pain medications when used alongside other treatment methods for chronic lower back pain.”

Chronic lower back pain, which is defined as moderate to severe pain in the lower back lasting longer than three months, is one of the most common chronic pain conditions in the U.S. Chronic pain may inhibit mobility or daily activities and has been linked to anxiety and depression, poor perceived health or reduced quality of life and dependence

Content current as of:
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Low Back Pain



Non-Immersive
2D VR



Immersive 3D
Distraction VR



Immersive 3D
Skills-Based VR



- ✓ Psychoeducation
- ✓ Pain education
- ✓ Breath training
- ✓ Relaxation training
- ✓ Executive functioning

VR Analgesia Procedure

1

Assess Appropriateness



2



Establish Set and Setting

3

Administer Treatment



4



Debrief

IBS VR

Developed at Cedars-Sinai; no external funding received

Qualitative Validation of a Novel VR Program for Irritable Bowel Syndrome: A VR1 Study

Brennan M.R. Spiegel, MD, MSHS^{1,2}, Omer Liran, MD¹⁻³, Rebecca Gale, MPH¹, Carine Khalil, PhD¹, Katherine Makaroff, BS¹, Robert Chernoff, PhD³, Tiffany Raber, MS, BFA⁴, Bianca Chang, MD², Nipaporn Pichetshote, MD² and Ali Rezaie, MD, MSc²

INTRODUCTION: Although gut-directed psychotherapies are effective for irritable bowel syndrome (IBS), they are rarely prescribed, given a paucity of trained clinicians. Virtual reality (VR) offers a solution by allowing patients to self-practice these techniques in a standardized manner.

METHODS: A multidisciplinary team developed IBS/VR, a program that transports users into immersive VR worlds that teach patients about the brain-gut axis, cognitive behavioral therapy, and gut-directed meditation. We tested IBS/VR in Rome IV IBS patients and used inductive analysis to evaluate perceptions and identify recommendations.

RESULTS: We achieved thematic saturation after 9 interviews; 3 additional interviews revealed no emergent themes. After making 23 software changes based on patient feedback, we conducted 3 additional interviews which confirmed thematic saturation (N = 15 total).

DISCUSSION: This study offers initial validation of the first VR program designed for IBS.

Am J Gastroenterol 2022;00:1–6. <https://doi.org/10.14309/ajg.000000000001641>

INTRODUCTION

Irritable bowel syndrome (IBS) is among the most common gastrointestinal disorders worldwide. Although IBS pathogenesis is multifactorial, its overlap with psychological comorbidities, coupled with evidence that neuromodulators and gut-directed psychotherapies are effective, indicates that IBS is a disorder of gut-brain interaction (1–5). Despite extensive data revealing that cognitive behavioral therapy (CBT), meditation, and gut-directed hypnotherapy are effective for IBS (2–5), these treatments are rarely prescribed, given a paucity of clinicians trained in behavioral techniques.

Therapeutic virtual reality (VR) offers a unique solution. Users of VR wear a head-mounted display that creates a vivid perception of being transported into immersive and emotionally evocative worlds. VR has been used to treat anxiety, depression, and pain (6–11). In gastroenterology, VR lowers endoscopic analgesia requirements and reduces pain from dyspepsia and sphincter of Oddi dysfunction (12–20). Although use of VR for IBS has been proposed (21), there are no IBS-specific programs nor any programs devoted to gut-directed CBT.

The US Food and Drug Administration (FDA) recognizes medical extended reality (MXR) as a novel field of medicine that uses VR software (22). Using the FDA Phase I-III drug development process as a guide, an international working group published a framework that divides MXR validation into 3 steps, called VR1, VR2, and VR3 (23). In a VR1 study, researchers use

human-centered design principles to develop software together with patients. Next, the VR2 study evaluates software usability, acceptance, and potential adverse consequences in clinical practice. Finally, the VR3 study is a randomized controlled efficacy trial. MXR validation depends on a successful VR1 study; in the absence of obtaining early feedback from patients, subsequent VR2 and VR3 validation is undermined.

In this brief communication, we describe a VR1 study for “IBS/VR,” an MXR program designed for IBS psychotherapeutic support.

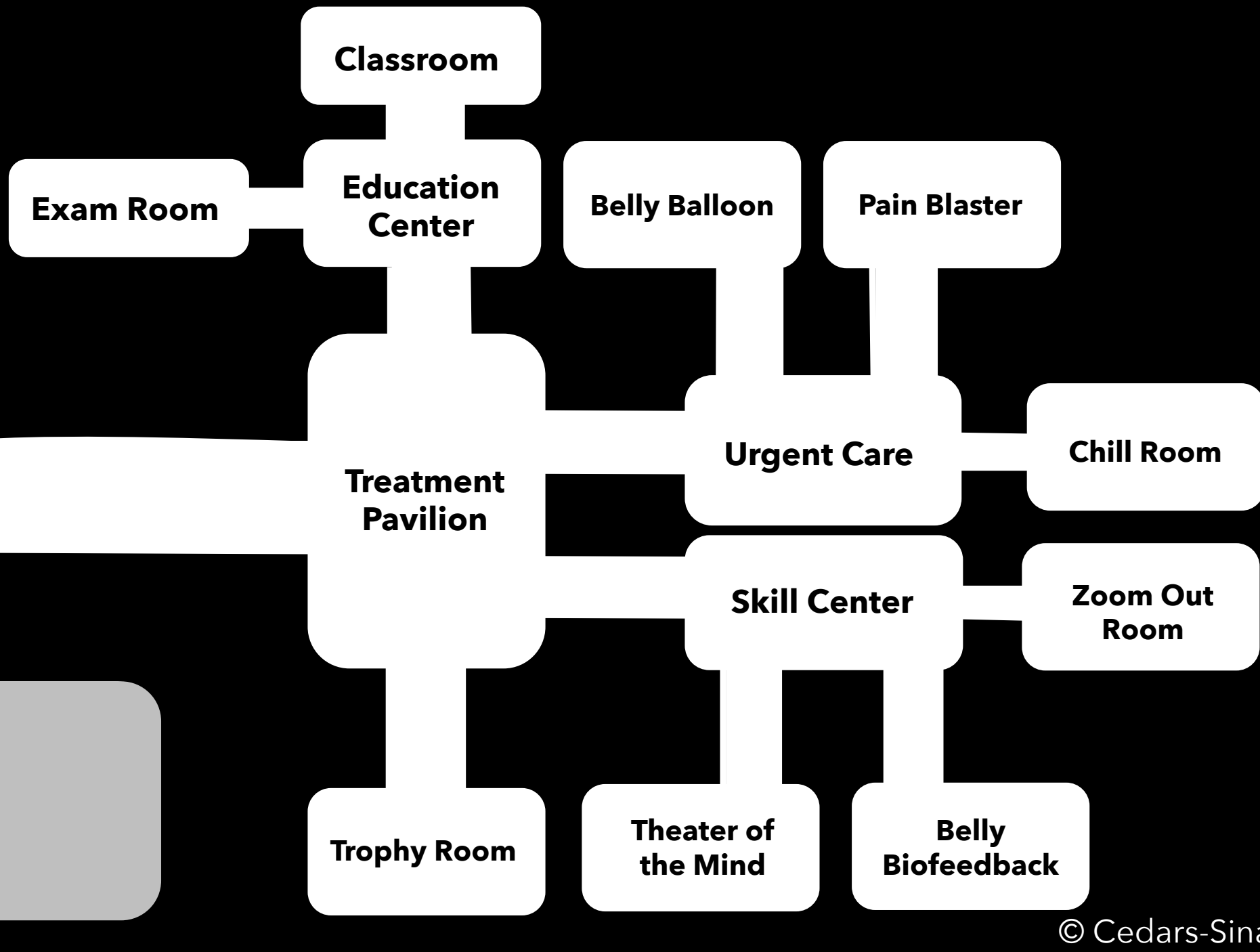
METHODS

Description of IBS/VR program

IBS/VR was developed by a multidisciplinary team including a CBT psychologist (R.C.), psychiatrist (O.L.), gastroenterologist (B.M.R.S.), biomedical visualization specialist (T.R.), MXR programmer/developer (O.L.), human-centered design expert (C.K.), and digital health researchers (R.G. and K.M.) to deliver psychotherapy within unique virtual environments. Applying the model of gut-directed psychotherapies described in the ACG IBS guidelines (5), we developed 4 virtual environments: (i) an immersive experience about the brain-gut axis (“Exam Room”); (ii) an IBS-specific CBT module (“Theater of the Mind”); (iii) a gut-directed meditative environment (“Chill Room”); and (iv) an environment addressing IBS-related social isolation and stigma (“Zoom Out Room”). Figure 1 shows a map

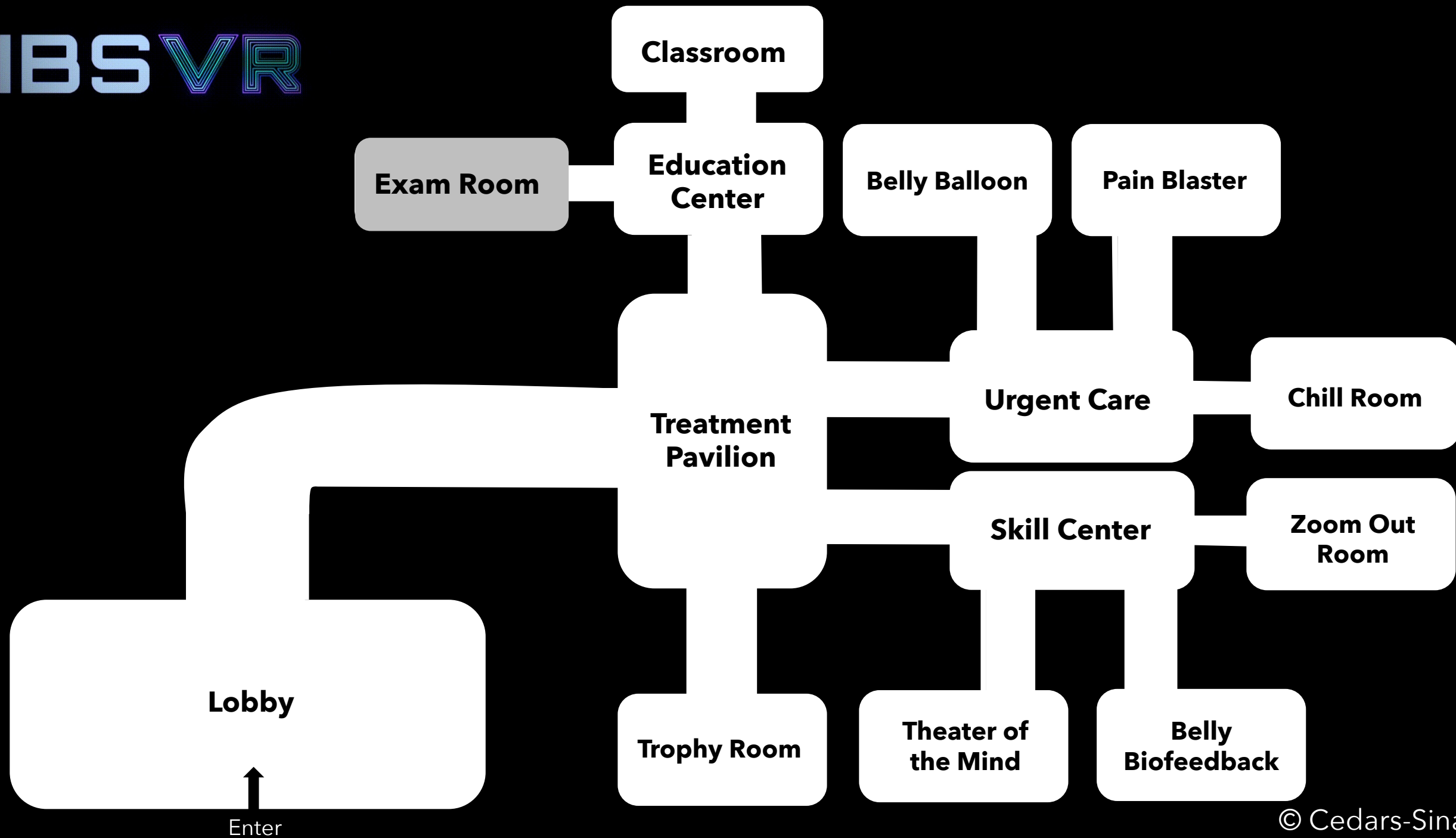
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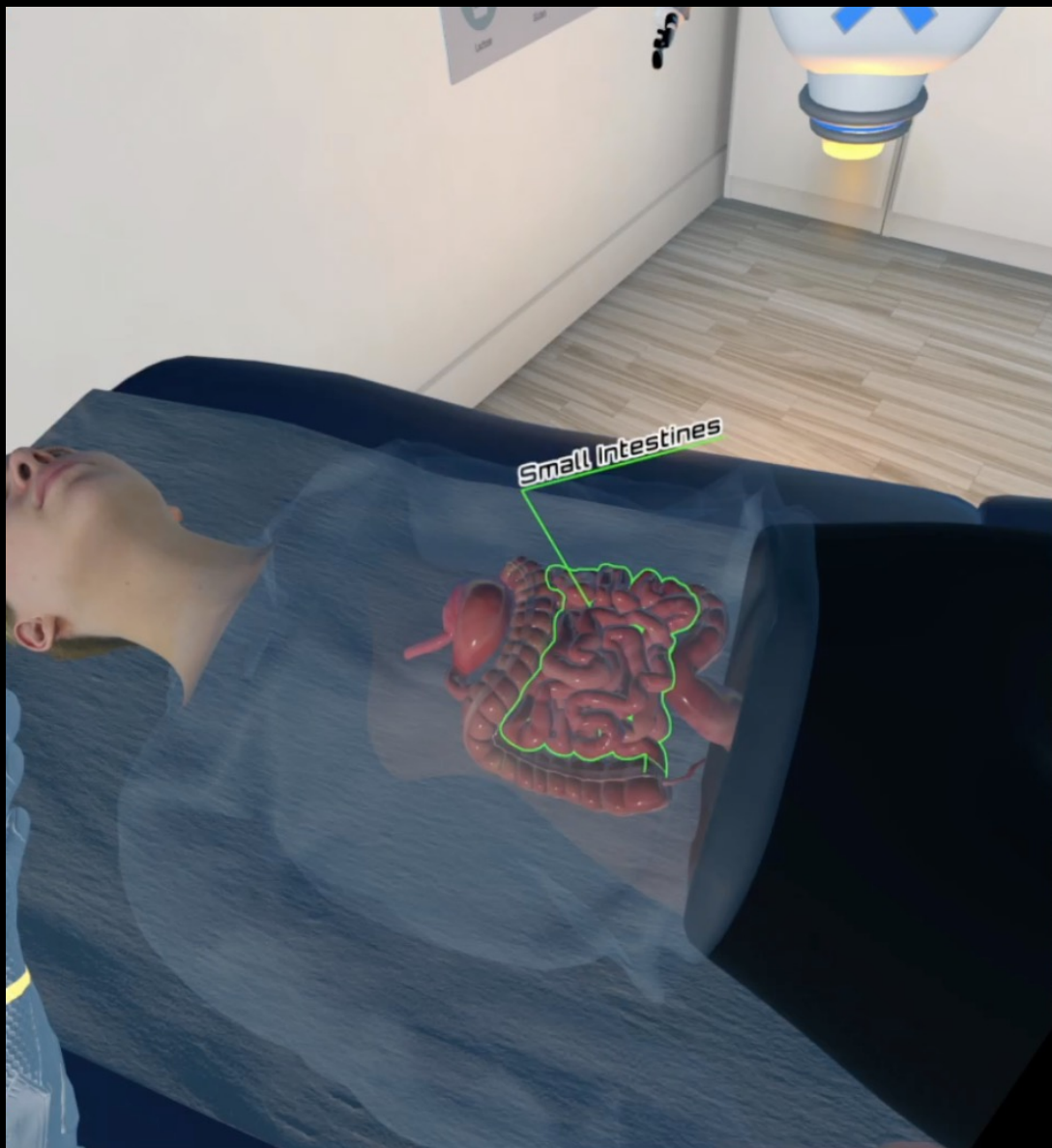


IBSVR

The Next Generation in Drug-Free IBS Therapy







Classroom



Pain Blaster

nt Care

Chill Room

Center

Zoom Out
Room

Lobby



Trophy Room

Theater of
the Mind

Belly
Biofeedback

VR_x

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Thank you!



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