

# Clinical Research

## Clinically-Validated, Safe, And Effective Pain Relief

The RelieVRx® program is a Class II FDA authorized medical device built on a foundation of clinical rigor to ensure the delivery of safe, effective, and evidence-based care.¹This clinically validated program has been shown to reduce pain intensity and interference for chronic lower back pain (CLBP) without the risks or burdens associated with other common treatment methods. Its lasting efficacy has been demonstrated in two randomized controlled trials involving over 1,200 patients.²³³⁴

There are no known contraindications.<sup>5</sup>

## Efficacy Validated Through Decentralized Randomized Controlled Trials 2,3

	Pivotal Post-Launch		
Sample Size	188	1067	
Demographics	Homogeneous	Diverse	
Clinical Severity	Moderate (4 to 6 out of 10)	Severe (≥7 out of 10)	

18+, self-reported non-malignant CLBP, average pain intensity > 4/10 over the past 3+ months. (6+ years of CLBP on average)

## **Extensively Studied Across A Diverse Population**

The RelieVRx program has been extensively studied across a broad population of clinically moderate to severe patients with CLBP.<sup>2,3</sup>

RelieVRx Treatment Group	Pivotal (n=94)	Post-Launch (n=536)	
Baseline Pain Intensity	5.1	6.6	
Baseline Pain Interference	4.8	6.2	

	Pivotal		Post-Launch	
Demographics <sup>6</sup>	RelieVRx	Sham VR*	RelieVRx	Sham VR*
Age (Average, years)	51.5	51.4	50.4	51.1
CLBP (years)	6.8	7.2	6.8	6.4
Gender(Female, %)	75	77.3	76.7**	68**
Race (Non-Caucasian, %)	10.7	4.7	30.9	33.9
Highest education level (High school or less, %)	7	10	19	20
Income (\$60K or less, %)	52	44	58	58

\*Sham VR is 2D nature content delivered in a VR headset.
\*\*The gender ratio differed significantly across RelieVRx and Sham VR.

**Scan the QR codes** on the right to learn more about our clinical trials.

Pivotal Clinical Trial

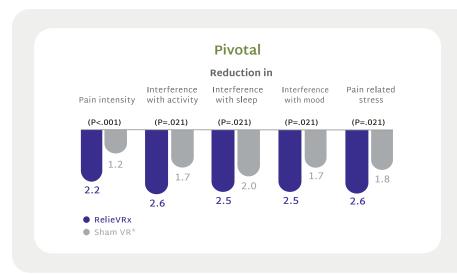


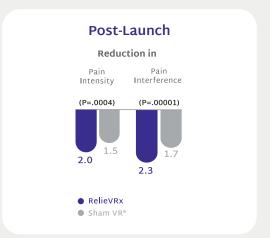
Post-Launch Clinical Trial



## Significantly Reduces Pain After 56-Session Program

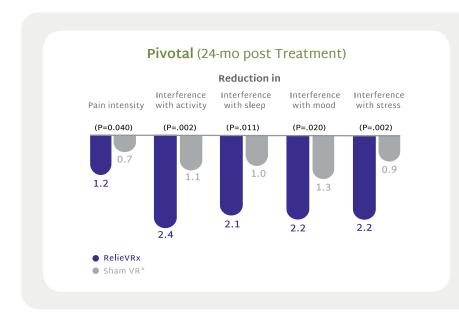
At the end of the 56-session program, significant pain reduction was seen by those who used RelieVRx compared to the Sham VR\* headset.<sup>2,3</sup>

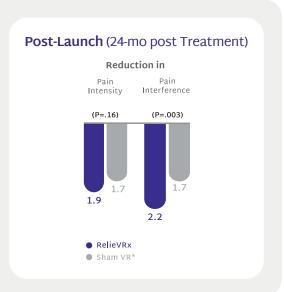




## Delivers Significant Benefits Up To 24 Months

Significant and lasting pain reduction observed by those who use RelieVRx compared to Sham VR\* headset, up to 24 months after single course of treatment.<sup>4,7</sup>





#### The RelieVRx Program Is Low-risk, Engaging, And Easy To Use

• Reported serious adverse events<sup>2</sup>

A+ Usability Rating<sup>7</sup> Average RelieVRx sessions per week in the Pivotal Trial<sup>2</sup>

4.7 Average RelieVRx sessions per week in the Post-Launch Trial<sup>3</sup>

<sup>\*</sup>Sham VR is 2D nature content delivered in a VR headset.

<sup>1. &</sup>quot;Device Classification under Section 513(F)(2)(De Novo)." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=764583&lpcd=QRA 2. Garcia LM, Birckhead BJ, Krishnamurthy P, Sackman J, Mackey IG, Louis RG, Salmasi V, Maddox T, Darnall BD. An 8-Week Self-Administered At-Home Behavioral Skills-Based Virtual Reality Program for Chronic Low Back Pain: Double-8lind, Randomized, Placebo-Controlled Trial Conducted During COVID-19. J Med Internet Res. 2021 Feb 22;32(3)26292. 3. Maddox, T., Oldstone, L., Sparks, C., Sackman, J., Oyao, A., Garcia, L., Maddox, R., Ffrench, K., Garcia, H., Irvin, A., Maislin, D., Keenan, B., Bonakdar, R., & Darnall, BD (2023). In-home virtual reality program for chronic lower back pain: A randomized sham-controlled effectiveness trial in a clinically severe and diverse sample. Mayo Clinic Proceedings: Digital Medicine, 2023;1(4):563-573. 4. Maddox, T., Sparks, C., Oldstone, L., Maddox, R., Ffrench, K., Garcia, H., Krishnamurthy, P., Okhotin, D., Garcia, L., Birckhead, B, Sackman, J., Mackey, I., Louis, R., Salmasi, V., Oyao, A., & Darnall, BD (2023). Durable chronic low back pain reductions to 24-months post-treatment for an accessible, 56-session, in-home behavioral skills-based virtual reality program: A randomized controlled trial. Pain Medicine. 5. RelieVRx (instructions for use). Van Nuys, CA: AppliedVR, Inc.; 2023. 6. Internal Data on File. 7. Internal data on file pending publication. 8. Lewis JR, Sauro J. Item Benchmarks for the System Usability Scale. Journal of Usability Studies. 2020;15(3):143-167. Available at: https://uxpajournal.org/item-benchmarks-system-usability-scale-sus/