

Remote cognitive behavioral therapy utilizing an in-home virtual reality toolkit (Vx TherapyTM) reduces pain, anxiety, and depression in patients with chronic cervical and lumbar spondylytic pain: A potential alternative to opioids in multimodal pain management

Matthew J. McGirt MD¹

Christopher M. Holland MD, PhD¹

S. Harrison Farber MD²

Scott L. Zuckerman MD, MPH³

Michael S. Spertus, MD⁴

Nicholas Theodore MD⁵

Deborah Pfortmiller PhD¹

Gerry Stanley MD⁶

¹ *Carolina Neurosurgery & Spine Assoc, Atrium-Wake Forest University, Charlotte, NC*

² *Department of Neurosurgery, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, AZ*

³ *Department of Neurosurgery, Vanderbilt University, Nashville, TN*

⁴ *Whole Health in Pain Medicine, Miami Veterans Affairs Healthcare System, Miami, FL*

⁵ *Department of Neurosurgery, Johns Hopkins University, Baltimore, MD*

⁶ *Harvard Med Tech, Las Vegas, NV*

Corresponding Author:
Matthew J McGirt MD
Carolina Neurosurgery & Spine Assoc.
225 Baldwin Ave, Charlotte, NC 28205
Charlotte, NC 28207
Matt.mcgirt@cnsa.com

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ABSTRACT

Objective: Virtual reality (VR) reduces pain through visual and auditory distraction, as well as altered brain neurobiology, but does so without narcotic-related side effects or pharmacologic dependency. Cognitive behavioral therapy (CBT) improves pain-related anxiety, depression, physical disability, resiliency and quality of life. However, access to CBT remains a challenge in most care communities. We hypothesized that in-home, remote weekly CBT coordinated with daily use of a proprietary VR toolkit will reduce pain, anxiety and depression for patients with non-operative chronic degenerative neck/back pain.

Methods: 145 patients with chronic degenerative neck/back pain (63 cervical, 46 non-radicular lumbar, 36 radicular lumbar) were enrolled into a guided 14-week VR + CBT program (Vx Therapy™) consisting of weekly telephonic calls with a trained therapist and 50 modules. Pain and anxiety severity scores (0 best, 10 worst) were recorded by patients before and immediately after VR use, as was time to pain recurrence. PROMIS measures (100 best, 0 worst) of overall daily pain intensity, pain behavior, pain interference, anxiety, and depression were recorded at baseline and at conclusion of the program.

Results: Mean score for all PROMIS domains were significantly improved after 14 weeks of Vx Therapy vs baseline (pain intensity 36 ± 24 vs 28 ± 21 , pain interference 39 ± 25 vs 24 ± 21 , pain behavior 35 ± 21 vs 25 ± 16 , anxiety 51 ± 28 vs 41 ± 26 , depression 58 ± 32 vs 48 ± 32) for the entire cohort and each diagnosis group. VR acutely reduced pain during use on average by 33% (4.5 ± 2.5 vs 6.7 ± 2.2 , $p<0.05$) across all 14 weeks, lasting a mean 2.8 hours after use. Duration of pain relief efficacy increased by the final vs. first month (4.5hr vs. 2.5hr, $p<0.05$). VR use acutely reduced anxiety during use on average by 46% (3.5 ± 3 vs 6.4 ± 2 , $p<0.05$) across all 14 weeks lasting a mean 2.7 hours after use. The effect was similar for all three groups.

Conclusions: Use of a remote CBT guided in-home VR toolkit provided effective and sustained pain relief in patients with chronic degenerative neck/back pain with and without radiculopathy. Fourteen weeks of Vx Therapy resulted in significant improvement in overall pain, anxiety, and depression and reduced pain interference with physical and recreational activities. The non-invasive, non-pharmacological nature of Vx Therapy makes it an ideal option for pain management in the post-opioid epidemic era.

Abbreviations: CBT, Cognitive behavioral therapy; US, United States; Virtual reality, VR; Virtual reality therapy, VRT

Introduction:

Virtual reality (VR) is a rapidly developing technology that creates a fully immersive experience for the user in a 3-dimensional computer-generated environment. A head mounted display worn by the user integrates visual and auditory stimuli to create an immersive virtual world. Initially, VR technology was developed by the US Military for training, and quickly gained favor within the gaming industry. It has subsequently been developed as a tool for training in clinical settings such as surgical education in orthopedic and neurosurgical procedural training.^{1,2} The clinical applications of VR are expanding as well; its use has been demonstrated in the treatment of pain and psychiatric disorders, as well as for physical rehabilitation.³⁻⁶ Recent examples include VR use for patients with both acute and chronic pain, cancer pain, and during painful medical procedures.⁷⁻¹⁷

Pain and psychiatric health conditions represent a major health burden demanding substantial resource utilization and frequent healthcare encounters. Approximately 100 million people in the United States (US) are affected by chronic pain.¹⁸ The economic burden of chronic pain through both direct costs and lost productivity has been estimated to be as high as \$600 billion dollars, greater than the costs of diabetes, heart disease, and cancer.¹⁸

Medication and invasive procedures have long been a cornerstone of pain management. As our understanding of the science of chronic pain has evolved, however, in addition to the opioid epidemic of the last decade, it has become clear that non-invasive, non-pharmacologic treatment options are desperately needed. Most major guidelines now recommend treating chronic pain from a multidisciplinary, multimodal approach that emphasizes non-pharmacologic treatments.¹⁹ Examples of multi-modal treatments include physical therapy and exercise, lifestyle and behavioral modifications, and psychological therapies.^{20,21}

Cognitive behavioral therapy (CBT) is the gold standard psychological therapy with evidence supporting its use for chronic pain and associated anxiety, depression, and physical disability.²² The positive effects of CBT and other psychological therapies on improving chronic pain including chronic back pain are well validated.²³⁻²⁵ However, access to CBT remains a challenge in most care communities as it relies on the presence of trained care providers and adequate transportation is necessary for in-person encounters. Furthermore, poor engagement with these trained providers limits not only access but programmatic success.

Harvard MedTech Vx Pain Relief Program (Vx Therapy TM) is a remote CBT that utilizes an in-home VR toolkit that connects the patient with virtual reality programming and directed guidance through the program by a behavioral health clinician. This system obviates the need for in-person health visits by generating a patient-specific virtual world in the patient's own home thus representing a paradigm-shifting modality for patients with pain. In a cohort of patients with non-operative degenerative neck/back pain, we hypothesized that in-home, weekly CBT delivered through a proprietary VR toolkit would reduce pain, anxiety, and depression over a three-month treatment period.

Methods:*Vx TherapyTM*

The Harvard MedTech Vx Pain Relief Program (Vx TherapyTM) is a physician prescribed 3-month therapeutic curriculum that consists of home-based Virtual Reality Therapy (VRT). This program includes weekly telephonic visits to direct cognitive-behavioral intervention therapies (CBT) with a masters-level behavioral health clinician (Vx NavigatorTM) who is assigned to each patient after completion of an initial clinical intake. The virtual reality headset is mailed to the patient's home. Therapeutic interventions are individualized for each patient during their weekly telephonic calls based upon their symptoms in order to attain optimal patient outcomes.

VRT hardware is a PICO headset pre-programmed with proprietary software designed and curated by Harvard MedTech. While wearing the headset and earphones, patients are fully immersed through visual and auditory stimuli in a non-internet connected environment. The VRT program includes 20 hours of content, organized as 3-20 minute immersive audio-visual modules in four categories: Education, Meditation, Distraction, and Escape/Entertainment (Figure 1). To maximize the benefit of the Vx Platform, patients (with guidance from their Vx Navigator) can select their environments, settings, and educational content to optimize their immersion. The curated content is delivered to the patient in an organized manner by their Vx Navigator to move the patient into the VRT with personalized goals based upon their individual needs. In addition to helping patients understand their symptoms, the navigator directs the patients to specific content and suggests when they should watch it to best use the program to facilitate their recovery. The content is designed to minimize vertigo, but patients are instructed

to participate in the program while seated at a desk or table and to remove the Vx Therapy Platform should they experience vertigo or associated symptoms.

Outcome Measurement and Analysis

From 08/2020-03/2023, patients insured under a variety of worker's compensation plans were eligible to be prescribed Vx Therapy as a non-invasive, non-pharmacologic treatment for chronic or subacute pain syndromes of any etiology. As a part of the standard of care of Vx Therapy, pain and anxiety severity scores (0 best, 10 worst) were recorded prospectively by patients before and immediately after VRT use, as was time to pain recurrence. This data was communicated to their Vx Navigator during weekly sessions. PROMIS measures (100 best, 0 worst) of overall daily pain intensity, pain behavior, pain interference, anxiety, and depression were also recorded in weekly telephone interviews from baseline through the conclusion of 14 weeks of Vx Therapy.

For the current study, the de-identified digital records of all patients undergoing Vx Therapy for a primary diagnosis of degenerative neck or back pain were retrospectively reviewed. Acute pain and anxiety scores before and immediately after in-home VRT were compared to determine the acute efficacy of VRT use. PROMIS measures at baseline and at conclusion of the 14 week Vx Therapy program were compared to determine the effectiveness of Vx Therapy at improving overall daily pain, anxiety, and depression associated with their degenerative spinal conditions. Univariate parametric data are reported as mean \pm SD. Bivariate comparative analyses were conducted using a paired t-test. Statistical significance was defined as $p < .050$.

Results:

145 consecutive patients were prescribed Vx Therapy for chronic cervical or lumbar pain over a 18-month period. Patients were referred from orthopedics, neurosurgery, psychiatry, and interventional pain clinicians. The patients were 52% male with an average age of 51 years of age. The majority of patients (70%) reported neck or back pain lasting greater than 2 years, while the remaining patients had symptom durations of less than 2 years.

Primary diagnosis was cervical spondylosis with neck pain in 63 patients (44%), lumbar spondylosis with axial back pain in 46 patients (32%), and lumbar spondylolysis with radiculopathy in 36 patients (25%). For each diagnosis group, baseline pain scores (range: 0-10) were 7.5, 5.8, and 5.0, respectively. Mean baseline pain-related anxiety scores (range: 0-10) were 6.8, 6.1, and 7.3 respectively. All patients completed their 14-week course of Vx Therapy.

Mean score for all PROMIS domains (range: 0-100) were significantly improved after 14 weeks of VRT vs baseline (pain intensity 36 ± 24 vs 28 ± 21 , pain interference 39 ± 25 vs 24 ± 21 , pain behavior 35 ± 21 vs 25 ± 16 , anxiety 51 ± 28 vs 41 ± 26 , depression 58 ± 32 vs 48 ± 32) for the entire cohort and for each diagnosis group, Table 1. VRT acutely reduced pain during use on average by 33% (4.5 ± 2.5 vs 6.7 ± 2.2 , $p<0.05$) across all 14 weeks (Figure 2a) lasting a mean 2.8 hours after use (Figure 2b). The duration of pain relief increased significantly when comparing the final (4.5hr) vs first month (2.5hr) of VR use ($p<0.05$). VR use acutely reduced anxiety during use on average by 46% (3.5 ± 3 vs 6.4 ± 2 , $p<0.05$) across all 14 weeks (Figure 3a) lasting a mean 2.7 hours after use (Figure 3b). The effect was similar for all three diagnosis groups, Figure 2a.

Discussion:

VR is an evolving technology with expanding applications in gaming, military and medical training, and clinical care. While some early studies have supported the use of VR in the treatment of acute and chronic pain, the efficacy in treating neck and back pain resulting from degenerative spondylosis is unclear. The present study adds to the currently sparse body of literature demonstrating the efficacy of VRT in both subacute and chronic pain syndromes.^{3,17} VR is thought to reduce pain through visual and auditory distraction, as well as alterations in brain neurobiology in several brain regions involved in the principle pain pathways. These effects are similar to those observed with opioid use, but without narcotic-related side effects or dependency.^{3,26-32}

The opioid epidemic in the US is a national crisis resulting in sky-rocketing mortality. In 2015, over 33,000 people died from opioid misuse and overdose.³³ Prescription opioid misuse has been reported in up to 4% of the adult US population.³⁴ Alternative non-pharmacologic treatment options are desperately needed to combat this trend. Cognitive behavioral therapy is one such non-invasive treatment option and is considered the gold standard psychotherapy that improves pain-related anxiety, depression, physical disability, resiliency and quality of life.^{22,35} However, access to CBT is a significant challenge for many patients given the shortage of trained behavioral health professionals and the costs of care. Moreover, patients are often unable to attend appointments due to physical, social or financial constraints, further limiting access to care.

The Vx Pain Relief Program (Vx TherapyTM) is a novel treatment paradigm that allows for remote CBT to be delivered in the patient's home via a VR device with specifically curated content. Vx Therapy utilizes a VR toolkit to connect patients with a behavioral health clinician

who develops a patient-specific treatment plan. The four domains of content that are included (Education, Meditation, Distraction, and Escape/Entertainment) are based on Level 1 data demonstrating their benefit in patients with chronic back pain.²³⁻²⁵ In this study, we evaluated the efficacy of this non-invasive, non-pharmacological treatment for patients with chronic degenerative cervical and lumbar pain. We found that this therapy significantly improved pain and anxiety scores for patients with neck and low back pain, as well as patients with lumbar radiculopathy. Pain and anxiety during Vx Therapy sessions were significantly decreased by an average of 33% and 46%, respectively across the study interval. These results were not only durable across the entire 14-week study period, but the duration of the effect increased over the course of the program, as well.

While the underlying neural mechanisms of pain control continue to be studied, one of the main functions of VR-based pain treatment is distraction such that the painful stimulus no longer receives the patient's attention. It is the immersive nature of the VR system that is able to effectively capture and maintain the patient's focus. The virtual world is able to compete with external painful stimuli and therefore decrease pain perception.³⁶ As such, a VR-based system is well poised to achieve the goals of traditional CBT to distract and decondition patients to negative stimuli to improve coping skills and overall function.³⁷ Vx Therapy delivers CBT remotely to patients in their own home and without the need for internet access such that they may undergo treatment even in resource-limited settings. Previous authors have expressed concern with the risk of habituation to VRT, as repeated exposures to treatment may lead to diminishing effects.³ However, in the current study no habituation occurred, with treatment effects lasting and even improving across the study interval.

There is limited literature regarding VR-based treatments for patients with spinal disorders. Sarig-Bahat et al. have previously shown that the addition of VR can increase cervical range of motion and improve pain scores in patients with neck pain.^{15,38,39} Another report of two patients with chronic low back pain found that VRT improved patient symptoms.⁴⁰ In comparison, the present study includes a larger patient population that demonstrated continued improvement in both pain and anxiety during treatments and included validated patient reported outcome measures. The patients in our cohort maintained benefit throughout the program and demonstrated, on average, increased duration of treatment effect with continued therapy.

This study is not without limitations. We performed a retrospective review of patients treated for chronic lumbar and cervical pain, and thus this methodology inherently limits the extent of analysis. However, all patient score data was collected in a prospective fashion as part of standard of care treatment. Patients were prescribed this therapy based on the discretion of the treating provider and did not undergo randomization. Moreover, while we demonstrated improved pain and anxiety scores up to 14 weeks with treatment, it will be important to assess the effects of VRT at longer term follow-up after the conclusion of the 14 week therapy program to determine if these effects are maintained. Finally, direct comparison of Vx Therapy to other modalities of pain treatment for degenerative cervical and lumbar pain including opioid and non-opioid medication, standard rehabilitation regimens, and invasive treatments such as injections will be important areas of future investigation.

Conclusion:

Use of a remote CBT guided in-home VR toolkit (Vx therapy™) provided effective and multi-hour sustained pain relief in patients with chronic degenerative neck and back pain with

and without radiculopathy. Fourteen weeks of Vx Therapy resulted in significant improvement in overall pain, anxiety, and depression and reduced pain interference with physical and recreational activities. The effective, non-invasive, non-pharmacological nature of VR therapy make it an ideal option to improve outcomes and resiliency in the modern landscape of pain management.

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Figure Legends:

Figure 1. Example content across the four categories of immersive audiovisual virtual reality modules: Education, Meditation, Distraction, Escape/Entertainment. **(A)** Educational courses are included to increase patient understanding of their underlying pathophysiology as well as to promote dialogue with their care team. **(B)** Guided meditations are successful because of the limited distractions that occur within the virtual environment. **(C)** Distraction content is designed to be both immersive and engaging to decrease thalamic activity. **(D)** Escape modalities are highly immersive from an experiential perspective but allow patients the freedom and self-actualization to control what and where they are escaping for their own entertainment.

Figure 2. (A) Average acute effects on pain severity immediately before and after using the Vx therapy virtual reality toolkit each day over the 14 week Vx therapy program for all patients. The use of Vx therapy modules via virtual reality headset resulted in acute reduction in pain (scale: 0-10). This effect persisted throughout 14 weeks. **(B)** Mean length of pain relief in hours after using the Vx Therapy virtual reality toolkit. Duration of pain relief after using the virtual reality toolkit increased throughout the 14 week program.

Figure 3. (A) Average acute Effects on anxiety immediately before and after using Vx Therapy virtual reality toolkit each day over the 14 week Vx Therapy program. The use of Vx Therapy modules via virtual reality headset resulted in acute reduction in anxiety (scale: 0-10). This effect persisted throughout the 14 weeks. **(B)** Mean length of anxiety relief in hours after using Vx Therapy virtual reality toolkit. Pain relief lasted an average of 3.5 hours after virtual reality toolkit use by week 14 of Vx therapy.

Table 1. Overall PROMIS (0 worst, 100 best) pain, pain behavior, pain interference, anxiety, and depression scores recorded at entry into and at 14 week conclusion of the in-home Vx Therapy program. A significant improvement ($p<0.05$) was observed across all diagnosis groups.

	Neck Pain	Back Pain	Lumbar Radicular Pain
Cohort Population Size	63	46	36
	Mean \pmSD	Mean \pmSD	Mean \pmSD
PROMIS Pain Intensity			
First Week	29.0 \pm 21.9	28.9 \pm 21.2	26.6 \pm 21.5
Last Week	34.8 \pm 27.2	36.4 \pm 22.9	35.3 \pm 24.6
PROMIS Pain Behavior			
First Week	24.7 \pm 14.7	24.4 \pm 15.3	26.7 \pm 18.2
Last Week	32.4 \pm 22.3	34.2 \pm 21.1	37.0 \pm 19.7
PROMIS Pain Interference			
First Week	25.2 \pm 21.6	24.4 \pm 21.4	22.9 \pm 21.3
Last Week	39.7 \pm 27.0	38.6 \pm 26.6	38.9 \pm 25.5
PROMIS Anxiety			
First Week	41.4 \pm 27.5	38.7 \pm 27.8	44.1 \pm 25.4
Last Week	52.7 \pm 27.6	48.9 \pm 30.2	52.3 \pm 31.0
PROMIS Depression			
First Week	50.8 \pm 30.3	44.3 \pm 34.2	49.9 \pm 33.9
Last Week	57.7 \pm 30.4	57.8 \pm 32.0	60.3 \pm 34.0

1A. Example content across the four categories of immersive audiovisual virtual reality modules: Education, Meditation, Distraction, Escape/Entertainment. (A) Educational courses are included to increase patient understanding of their underlying pathophysiology as well as to promote dialogue with their care team.



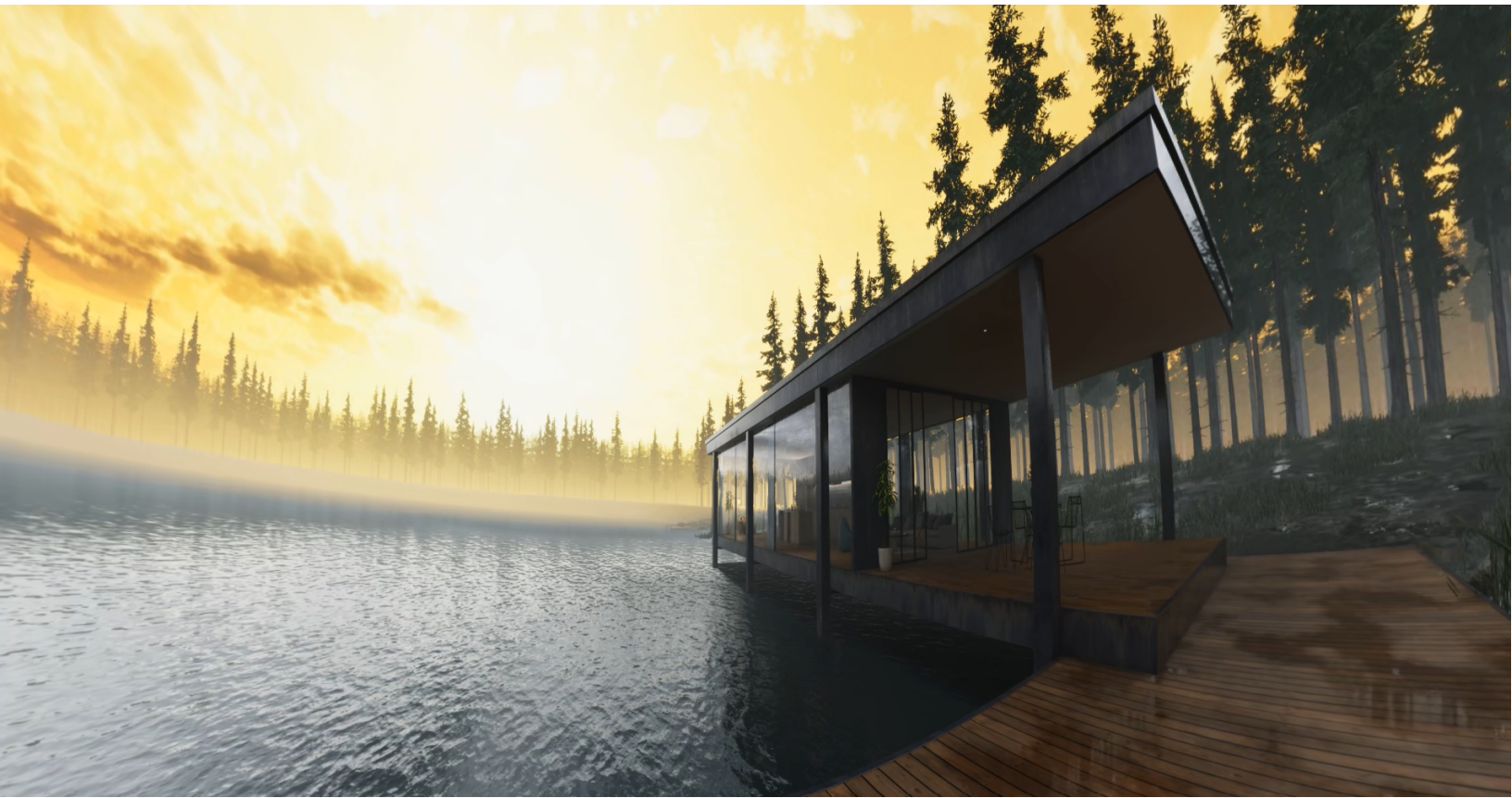
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1B. (B) Guided meditations are successful because of the limited distractions that occur within the virtual environment.



1C. (C) Distraction content is designed to be both immersive and engaging to decrease thalamic activity.

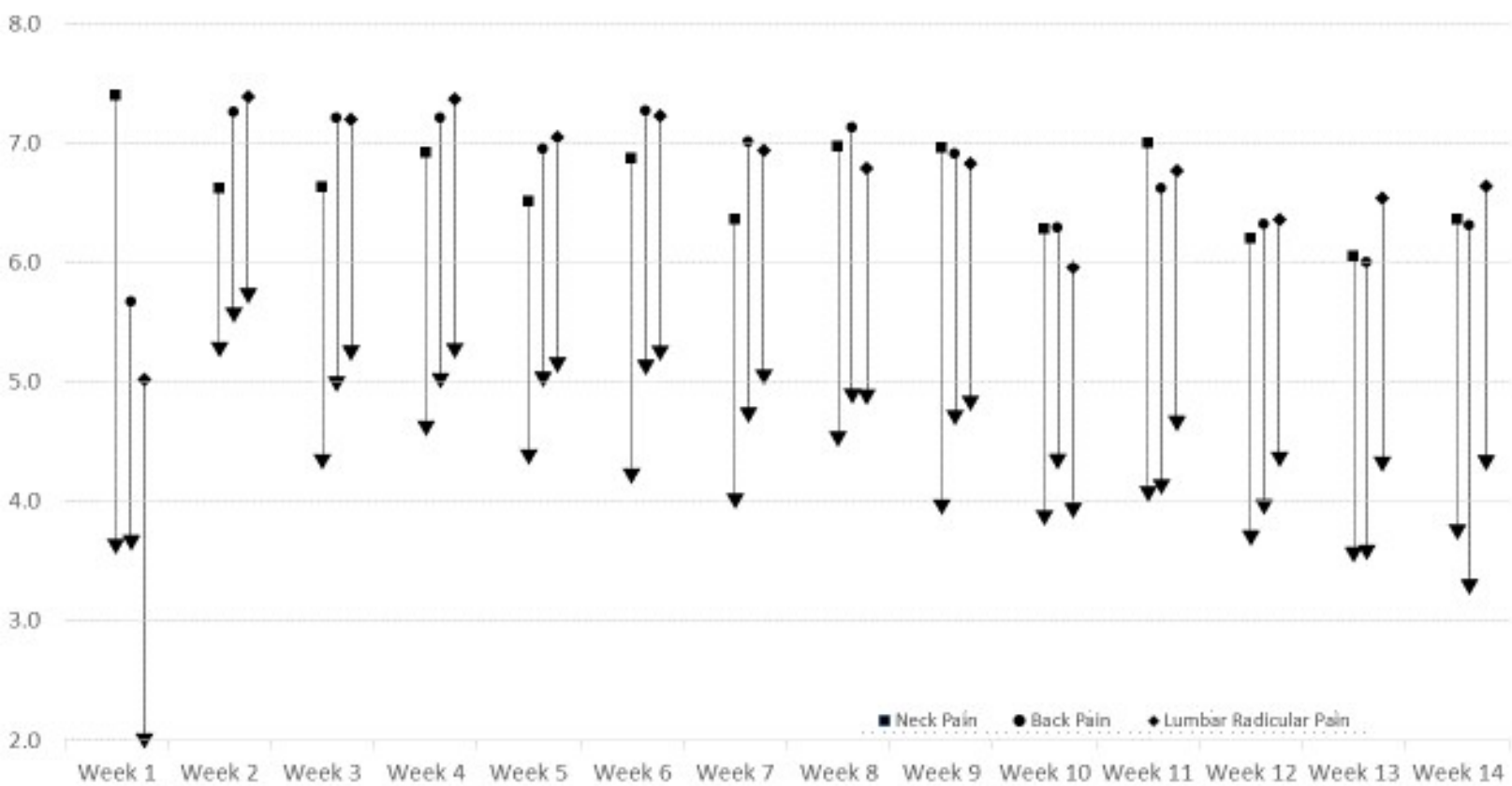


1D. (D) Escape modalities are highly immersive from an experiential perspective but allow patients the freedom and self-actualization to control what and where they are escaping for their own entertainment.



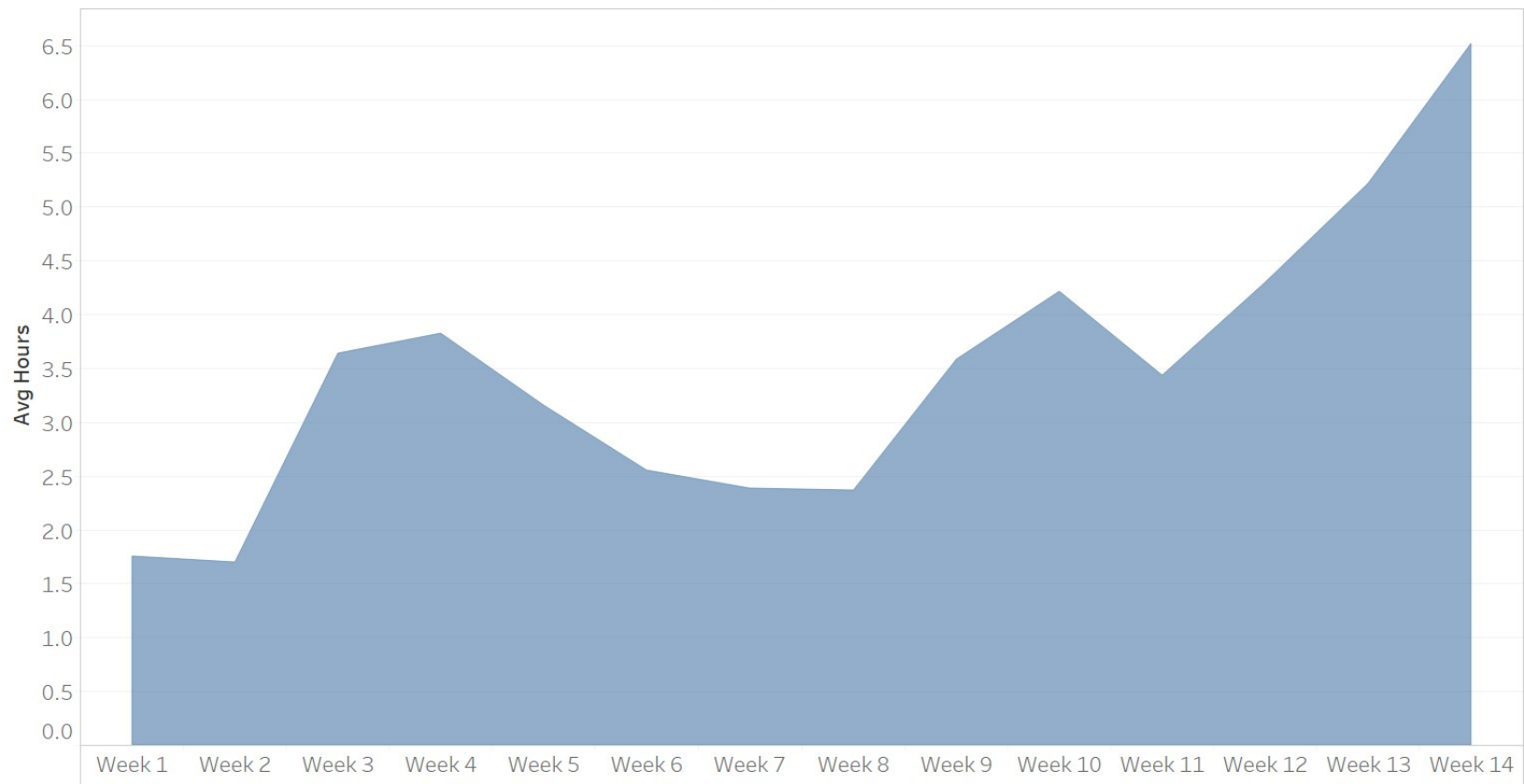
2A. (A) Average acute effects on pain severity immediately before and after using the Vx therapy virtual reality toolkit each day over the 14 week Vx therapy program for all patients. The use of Vx therapy modules via virtual reality headset resulted in acute reduction in pain (scale: 0-10). This effect persisted throughout 14 weeks.

Pain Acute Effects During VR-CBT



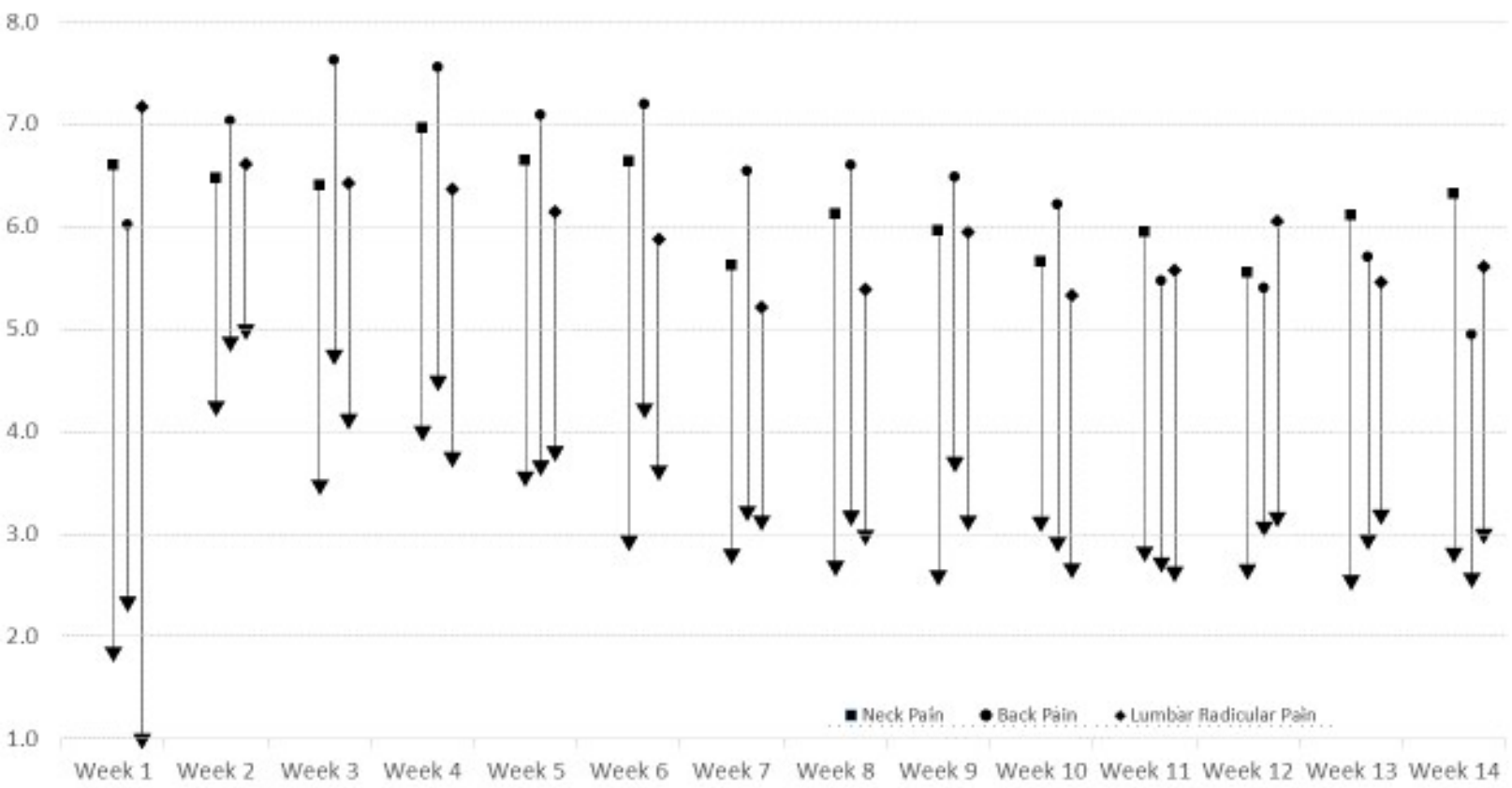
2B. (B) Mean length of pain relief in hours after using the Vx Therapy virtual reality toolkit. Duration of pain relief after using the virtual reality toolkit increased throughout the 14 week program.

Pain - Hours of Relief



3A. (A) Average acute Effects on anxiety immediately before and after using Vx Therapy virtual reality toolkit each day over the 14 week Vx Therapy program. The use of Vx Therapy modules via virtual reality headset resulted in acute reduction in anxiety (scale: 0-10). This effect persisted throughout the 14 weeks.

Anxiety Acute Effects During VR-CBT



3B. (B) Mean length of anxiety relief in hours after using Vx Therapy virtual reality toolkit. Pain relief lasted an average of 3.5 hours after virtual reality toolkit use by week 14 of Vx therapy.

Anxiety - Hours of Relief

