Analysis of a novel approach to solving pain: Combining Virtual Reality and Behavioral Health

A BioPsychoSocial Modality

ABSTRACT

A group of 20 patients with chronic debilitating pain were analyzed. Patient pain was the result of workplace injuries which left most patients unable to work. The patients' physicians prescribed the Harvard MedTech Vx Pain Relief Program which consists of a combination of home-based Virtual Reality Therapy (VRT) and behavioral health therapy through scheduled phone consultations. Each patient was uniquely paired with a behavioral health clinician chosen to address their specific needs. The clinicians tracked variables including pain levels reported both before and during home based VRT. In addition, patients set three personal goals that were meaningful for them to accomplish throughout the 90-day program. The patients experienced substantial pain relief from the first session which continued to improve throughout the course of 3 months and up to 12 behavioral health sessions. As a result of the combination of VRT and working with a behavioral health clinician, or the Vx Pain Relief Program, patients were able to reach their desired goals. Patients reported reduced depression, fatigue, and sleep disturbance. They learned to function with pain, reduced their anxiety related to pain and increased their ability to walk, do household tasks, participate in social roles and, potentially, return to work.

PREFACE

Chronic diseases, such as pain, have been a part of the human condition since the beginning of recorded time. Historically, a variety of approaches were taken to mitigate the impact and effects of chronic diseases. In the case of pain, this included traditional herbal remedies and external physical manipulations. It was in the 20th century, with the advent of pharmaceuticals, that more interventional and aggressive approaches started to be used. For pain mitigation, the aggressiveness of interventional approaches reached their peak, late in the 20th century, with the designation of pain as a 5th vital sign. Given the heightened sense of urgency to solve the problem of pain, with its elevated status as a vital sign, extremely aggressive pharmaceutical intervention strategies, using opioids, began to be deployed. Over the following decades, it became clear that aggressive opioid use was not the desirable solution that it was hoped to be. In addition to the challenge of increased patient tolerance building over time and requiring ever higher dosages, the undesirable side effects and addictive properties of opioids became clear. This set off a search for finding alternative modalities for pain mitigation that possessed sufficient analgesic properties and that did not possess the undesirable side effects of opioids.

Keywords:

Pain, Vx Cognitive Therapy, Virtual Reality Therapy, Vx Therapy, VRT, Cognitive Behavioral Therapy

Introduction

Pain can be debilitating, effecting both personal and professional productivity. Pain can also affect a person's psychology: depression, anxiety, fatigue, sleep disturbance, social withdrawal, even suicidal ideation may occur. Pain research has shown that pain is both a sensory and an emotional experience and is affected by psychological factors.[1] One often referenced theory is the Gate Control Theory of pain which was first proposed in 1965 by Ronald Melzack and Patrick Wall. The Gate Control Theory of pain suggests that alternative stimuli can reduce the intensity of physical pain by blocking pain messages at nerve gates in the spinal column.[2] The physiological sensation of pain from the peripheral nervous system may be blocked by psychological input to the brain.

There is ample evidence that the 3D immersive environment of Virtual Reality can be effective in reducing pain, and in fact, is more effective than distraction techniques using 2D screens.[3] Harvard MedTech has entered the market with a unique solution to manage pain. The Vx Pain Relief Program leverages Virtual Reality technology with behavioral health therapy to provide lasting, clinically significant relief from pain along with the behavioral changes needed to get the patient back to their normal work and social life.

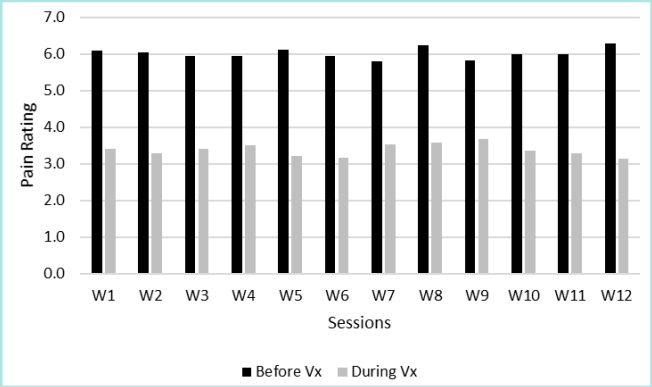
Cohort Report

In 2019, a group of 20 patients were on workers compensation for pain due to workplace injuries. The patients were treated between April 2019 through January 2020. The sample was composed of 9 males and 11 females. The average age at time of treatment was 53 with the youngest being 28 and the oldest 70. All patients were referred and overseen by a prescribing physician. Nine patients were referred by orthopedic specialists, 8 by pain specialists, and 3 by other. Programs resulted in the following: 11 graduated (completed the program), 4 reached the end of their 90-day period with under 10 sessions, 3 ended early due to claim related issues, and 2 terminated early due to unrelated health or family issues. Patients were selected based on session count and compliance. Patients needed to have attended at least 5 sessions with their behavioral health clinician, with interruptions in service attributed to claim-specific reasons.

The patients' physicians prescribed the Vx Pain Relief Program. They were enrolled in the home-based program for 90 days. A Vx headset containing proprietary software was provided and the patients were paired with a specialized clinician best suited to address each patient's behavioral health needs. The patients were instructed to use the headset at least 1-2 times a day, selecting specialized programs to provide relief for pain, increase knowledge about how pain works, teach them skill sets to cope with pain, reduce anxiety, and promote a healthier emotional state. Weekly phone consultations were scheduled with their clinicians. Each session ranged from 30-60 minutes with regular reevaluations. The clinicians directed the program, ensured compliance, and provided further education on how to generalize skills taught by the Vx headset. The clinicians shared this information with the physicians, who monitored the patients' progress.

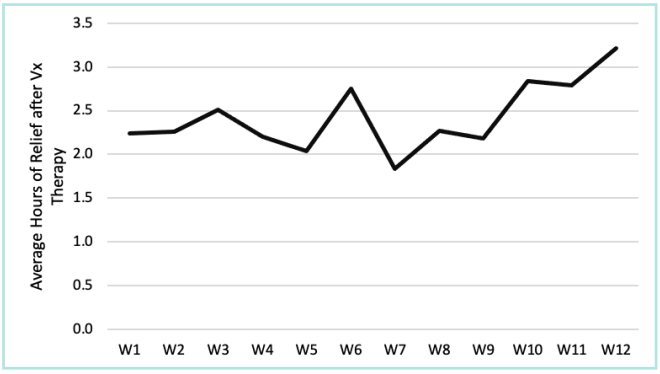
During each session, the patient reported his or her average starting pain level on a 1-10 scale. The patient then reported the pain level experienced during Vx Therapy. The patients had immediate results after the initial session. Pain levels were reduced, on average, 44% while the patients were wearing the Vx headset and using the specially selected programs. See Graph 1 (pg 3). Decreased pain levels during Vx Therapy use demonstrates the effectiveness of Vx Therapy as an analgesic.

Graph 1. Reduction in pain while using Vx Therapy



Patients in the Vx Pain Relief Program experienced significant legacy pain relief, see Graph 2 (below). The patients fell into three categories: those who experienced consistent relief after each session, those whose relief increased as sessions progressed and those who had varied results. On average patients experienced 2.4 hours of relief post treatment. It appears that a significant legacy

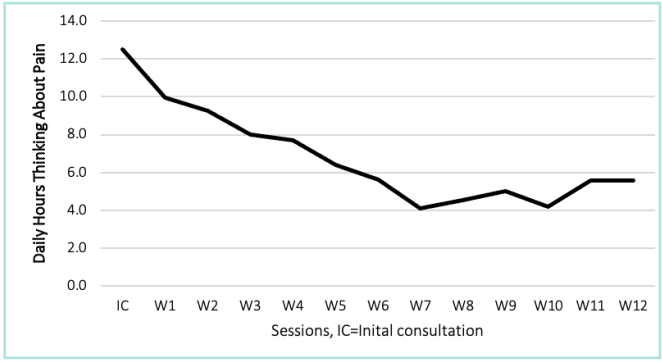
Graph 2. Avg Hours of Relief after Vx Therapy



period of pain relief is not only maintained over time but increases with additional sessions which demonstrates neuroplasticity and suggests patients do benefit from longer program duration.

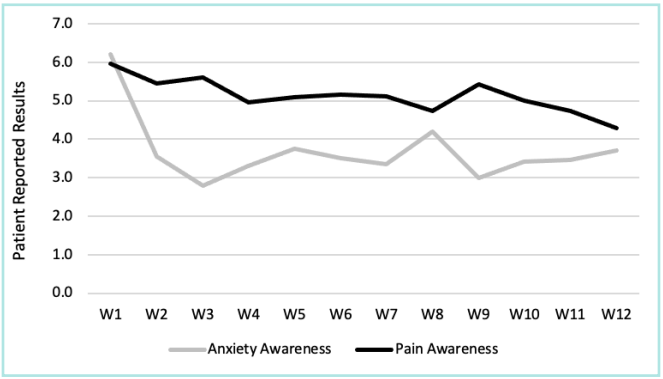
Patients in the Vx Pain Relief Program reduced the average daily time spent thinking about pain from 12.5 hours at the start of the program to 5.6 hours by discharge. See Graph 3 (top right). This represents a reduction in the number of hours per day spent thinking about pain. Reduction in time ruminating about pain means reduced risk of pain catastrophization and codification.

Graph 3. Daily Hours Thinking About Pain



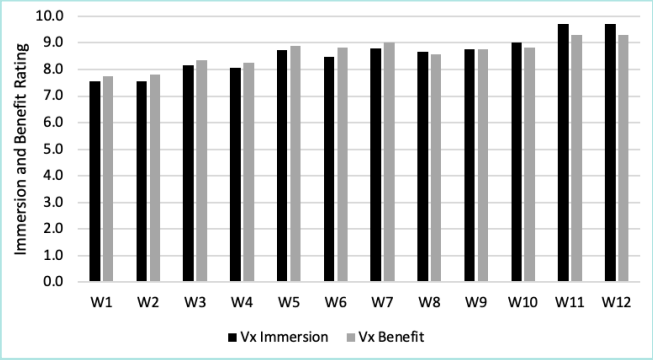
In addition, the patients experienced reduced anxiety awareness throughout the program. See Graph 4 (below). At the initial consultation, awareness of pain and anxiety appeared correlated, indicating that they were connected. As the patients began to manage their pain more effectively, they were able to experience pain without a spike in anxiety. This indicates that the Vx Pain Relief Program has effectively reduced the patients' physical pain and increased the patients' psychological well-being allowing the patients to reintegrate into daily life.

Graph 4. Pain and Anxiety Awareness



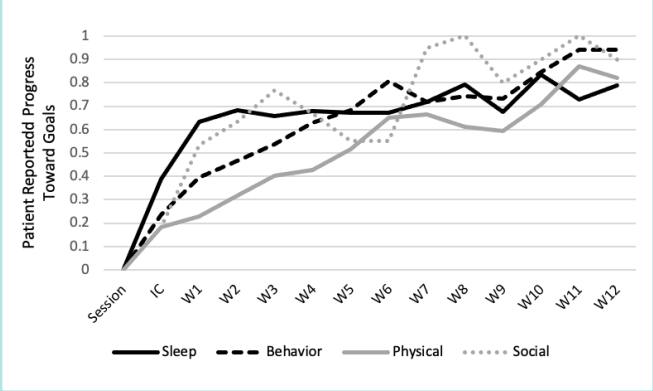
Patients reported high levels of immersion and perceived benefit, see Graph 5 (next page). This indicates the effectiveness of the proprietary software in capturing patient attention and setting the stage for neuroplasticity training, leading to increased pain resilience.

Graph 5. Patient Perception: Immersion & Benefit Rating



Patients were each asked to set three goals during the initial consultation. The goals could be behavioral, physical or social based. Improved quality and duration of sleep was chosen so often that this goal was analyzed separately. Enhancing quality and duration of sleep is critical for positive progress by pain patients. Patients experienced a 102% increase in quality and duration of sleep. Improving emotional and behavioral health can help pain patients regain a sense of control.

Graph 6. Patients Self-reported Goals



Patients were able to achieve a 297% increase in behavior-based goal achievement ratings. Looking at the physical-based goals is a great proxy for enhanced productivity and the ability to return to work. Patients targeting physical and mobility-based goals experienced an average improvement of 349% in goal achievement rating. Finally, resuming regular social interactions after an injury helps to restore feelings of normalcy, leading to an enhanced ability to return to work and effectiveness at work. On average, patients saw an increase of 390% in social-based goal achievement ratings from the time of initial consultation to discharge.

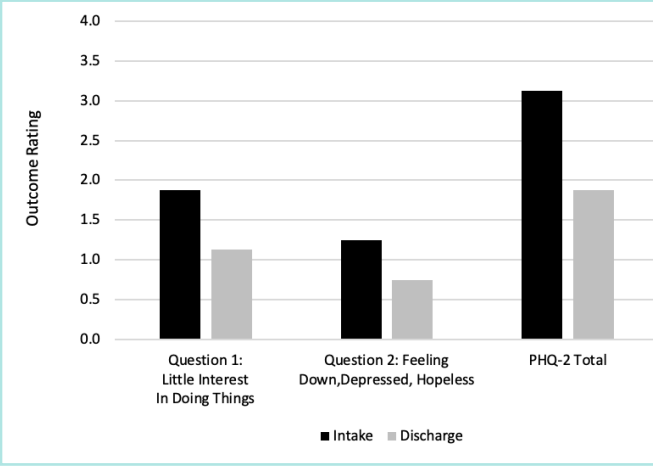
The clinicians questioned patients using the Patient-Reported Outcomes Measurement System-29 (PROMIS-29) instrument. Results were significant as seen in Table 1 (below). Patients saw a decrease in anxiety, depression, fatigue, sleep disturbance, pain interference and pain intensity which lead to higher physical function and participation in social activities. Patients experienced increases in physical function and the ability to participate in social roles and activities. Improved outcomes measures translate into an increased level of functioning, including at work.

Patients were questioned using a 2 question Patient Health Questionnaire (PHQ)-2. Question 1 asked about their interest in performing activities, question 2 asked about feeling down, depressed, or hopeless. The results from the initial consultation were compared to discharge, see Graph 7 (next page). The questionnaire showed a 40% improvement in positive thinking and pleasure in performing activities, whether work or social. This is gate theory at work - positive emotional state increases pain resilience.

Table 1. PROMIS-29: Result comparison from intake to discharge

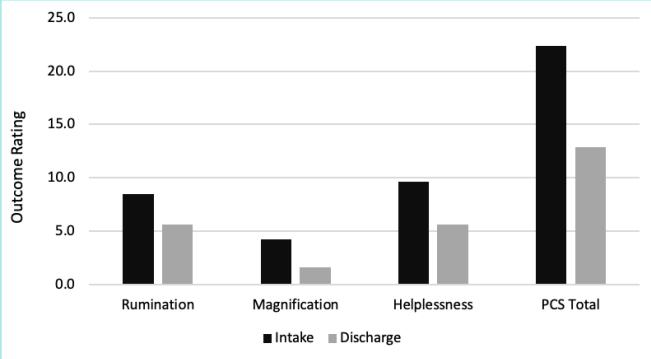
Areas	Intake	Discharge	% Improvement
Physical Function	11.8	14.1	20%
Anxiety	9.8	7.8	21%
Depression	9.3	6.8	28%
Fatigue	13.3	11.3	15%
Sleep Disturbance	14.0	12.9	8%
Ability to Participate in Social Roles and Activities	8.1	12.9	60%
Pain Interference	15.6	12.2	22%
Pain Intensity	6.1	5.4	12%

Graph 7. PHQ-2: Initial consultation compared to discharge



Patients were questioned during the initial consultation about pain rumination, pain magnification, pain helplessness. Patients were again questioned at discharge. The results are shown in Graph 8. (below). Patients experienced an overall improvement of 42% in pain catastrophizing symptoms with the highest improvement seen in the levels of pain magnification with a 62% improvement. Rumination improved 34% and helplessness improved 42%. Again, this is gate theory at work. Positive emotional state increases pain resilience.

Graph 8. Pain Catastrophizing Scale: intake compared to discharge



Discussion

Using specially designed VRT content in conjunction with behavioral health therapy, the Harvard MedTech Vx Pain Relief Program allowed patients to become more resilient. They learned to manage their pain and their anxiety related to pain decreased. This facilitated patients achieving their personal physical, behavioral and social goals.

Pain levels were reduced, on average, 44% while the patients were wearing the Vx headset and were using the specially selected "distraction" programs. Additionally, on average, patients experienced 2.4 hours of legacy pain relief post using the headset. Patients also saw a decrease in anxiety, depression, fatigue, sleep disturbance and pain interference which led to higher physical function and participation in social activities.

The Vx Pain Relief Program is an example of neuroplasticity and the Gate Control Theory at work. Repeated exposures to VRT content allow and promote neural rewiring (neuroplasticity) to occur over time, allowing for the analgesic benefits of distraction therapy to become hard wired, as evidenced by the increasing legacy time period of analgesic relief post exposure. Also, an improved emotional state was achieved through a combination of exposure to the "meditation" VRT content and the behavioral health interventions, resulting in increased pain resilience.

The Harvard MedTech Vx Pain Relief Program is an effective treatment for both pain and the psychological problems associated with pain. This translates into greater functional ability at work, or a decrease in the time needed to be able to return to work.

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