

Analysis of a Novel Approach to Resolving Pain in Work-Related Injuries: Combining Virtual Reality and Behavioral Health Interventions to Promote Pain Resiliency and Functionality

A BioPsychoSocial Modality

ABSTRACT

A group of 36 patients with chronic and acute pain were analyzed and treated. Patient pain was the result of workplace injuries which left most patients either unable to work or limited in their work capacity. The patients' physicians prescribed the Harvard MedTech Vx Pain Relief Program (Vx Therapy) which was a 3-month program consisting of home-based Virtual Reality Therapy (VRT) and weekly telephonic or telehealth behavioral health intervention visits. After an initial assessment, each patient was assigned a behavioral health clinician to address their specific needs based upon their injury and the therapeutic interventions necessary to obtain optimal results. These patients set three personal goals to accomplish throughout the 3-month program. The specific goals had to be meaningful to the individual patient and their progress towards these goals were tracked by their assigned behavioral health clinicians. The clinicians also tracked a series of clinical variables including pain levels reported before, during, and after Vx headset use. The patients experienced substantial immediate and lasting pain relief from the onset of therapy and throughout the course of the 3-month program. As a result of the Vx Therapy, patients were able to reach their desired goals. Additionally, patients reported reduced overall anxiety, fatigue, and sleep disturbance. They became more pain resilient and learned to function with pain and with reduced fear as it related to pain, they gained an increased ability to walk, do household tasks, and participate in their social roles. Over two-thirds of patients that were taking opioids at the start of the program were able to either decrease or cease the use of opiate medications. The ability to increase pain resiliency, reduce or eliminate pain medications, and return to normal activities of daily living, translates into greater work functionality and a higher likelihood of returning to work.

PREFACE

Chronic disease has been a part of the human condition since the beginning of recorded history. A variety of approaches have been taken to mitigate the impact and effects of

chronic diseases. In the case of pain, this included traditional herbal remedies and external physical manipulations. The advent of pharmaceuticals in the 20th century led to more interventional and aggressive approaches to the treatment of pain. 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”. A medical providers responsiveness to pain became a common quality metric used by health systems to evaluate the performance of the individual clinicians. Given the heightened sense of urgency to resolve the problem of pain, the prevalence of opioid prescriptions significantly increased. Over the following decades, it became apparent that aggressive opioid prescribing was not a desirable solution. In addition to the challenge of increased patient medication tolerance over time requiring ever higher dosages, the undesirable side effects and addictive properties of opioids became clear. This has led to the search for effective non-pharmacologic modalities for pain mitigation which possess efficacious levels of analgesic benefit, without the undesirable side effects of narcotics.

SUMMARY

Over the course of the 3-month Vx Therapy program, 69% of the patients that were taking opioids at the beginning of the program saw either a cessation (38%) or reduction (31%) in opiate use (opiates were being consumed by 16 out of the 36 patients in the study). Furthermore, with respect to all patients in the study, they reported an immediate 40% reduction in pain utilizing the Vx headset and an additional 2.8 hours of continued pain relief following use of the Vx headset. Additionally, patients reported a 28.6% reduction in the awareness of their pain and a 115% increase in the duration of their nightly sleep. Harvard MedTech’s Vx Therapy is an effective tool in the treatment of pain and the psycho-social issues associated with pain. This translates into a greater degree of pain resiliency and an overall improvement in general wellness, leading to improved workplace functionality and a decrease in the time needed to be able to return to work.

KEYWORDS

Pain, Pain Relief, Pain Alternatives, Opioid Reduction, Opioid Cessation, Vx Cognitive Therapy, Virtual Reality Therapy, VRT, Vx Therapy, Cognitive Behavioral Therapy, CBT, Workers Compensation, Occupational Medicine, Bio-Psycho-Social Model of Care Delivery, Telemedicine, Sleep, Pain Awareness, Anxiety, Depression

Introduction

Pain is both a sensory and an emotional experience and is affected by psychological factors.¹ Pain can be debilitating, affecting 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.

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.² One often referenced theory on how this is effective 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.³ The physiological sensation of pain from the peripheral nervous system may be blocked, or de-prioritized, by psychological inputs to the brain.

The Harvard MedTech Vx Pain Relief Program leverages a home-based proprietary virtual reality technology platform and headset with remote behavioral health interventions to provide lasting, clinically significant relief from pain along with the longitudinal behavioral changes needed to get the patient back to work and restore a sense of normalcy to their life.

Cohort Sample

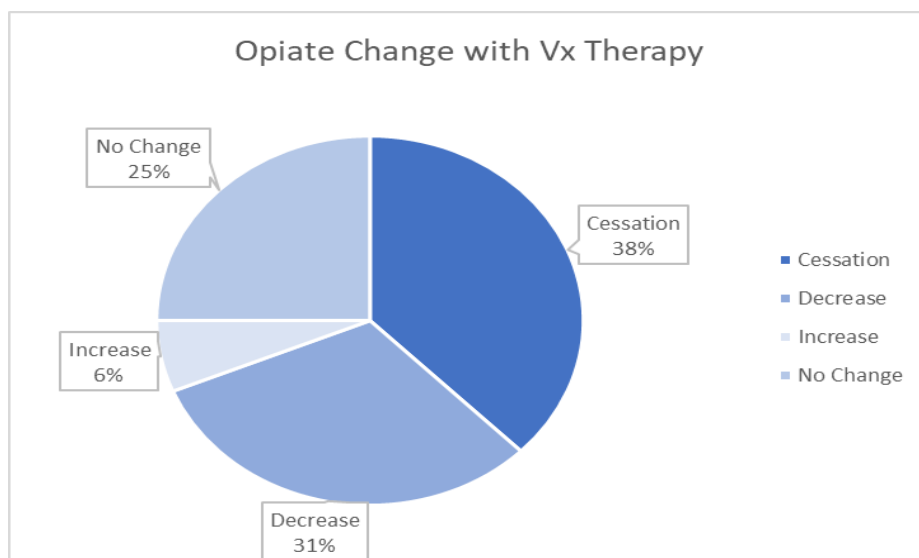
A group of 36 patients were on workers' compensation benefits for pain due to workplace injuries. The patients were treated between April 2019 through April 2020. The sample was composed of 16 males and 20 females. All patients were referred and overseen by a prescribing physician and were referred by orthopedic specialists, pain specialists, primary care providers, or occupational health providers. Patients were selected based on the number of weekly clinician sessions completed and program compliance. Patients needed to have attended at least 10 sessions with their behavioral health clinician and complete at least 12-weeks of the program.

The patients' individual physicians prescribed Vx Therapy. They were enrolled in the home-based program for 3 months (12 consecutive weeks). A Vx headset containing proprietary software was sent to the patient's home and they were onboarded into the program by their personal clinician. After the initial assessment, patients were paired with a specialized clinician best suited to address each patient's behavioral health needs and goals. The patients were instructed to use the headset initially for at least 1-2 times per 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 telephonic consultations were scheduled with their clinicians. The telehealth sessions ranged from 30-60 minutes with regular reevaluations based upon the psycho-social needs and goals of the patient. The clinicians directed

the program, ensured compliance, and provided further education on how to generalize skills that were learned by using the Vx headset. The personal clinicians shared this information with the prescribing physicians via weekly progress notes. Physicians provided remote patient monitoring and management to the patients, making changes to the treatment protocols and conversing with the personal clinician and the patient as needed.

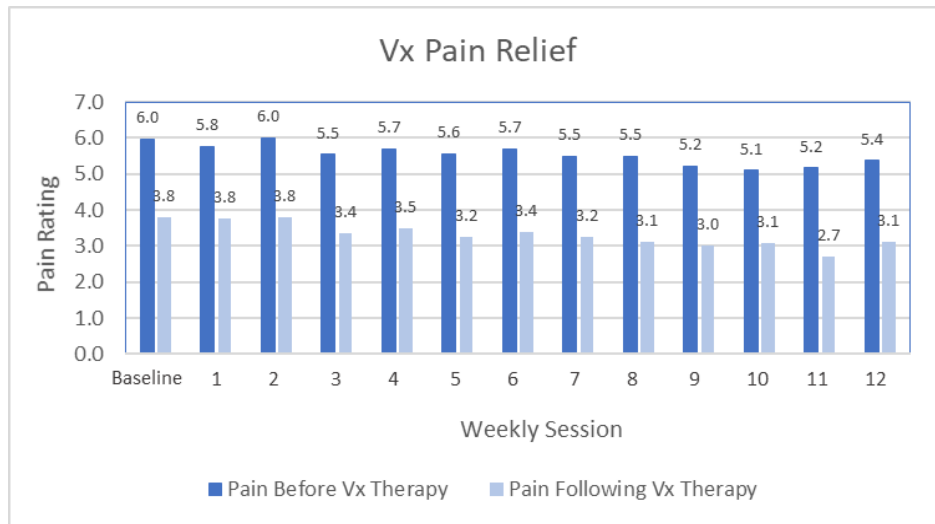
Cohort Report _____

During the course of the Vx Therapy program, patient medication usage was tracked to examine compliance and medication dose changes during therapy. Medications tracked included opiates, anxiety related, blood pressure related and sleep related medications. 69% of patients reported either a decrease in opiate use or a complete cessation of opiate use. See Graph 1. The decreased use of opioid medication during Vx Therapy is a strong indication of the program’s ability to cause neuroplastic change in the patient’s brain to assist in the reduction and cessation of opiate medications.



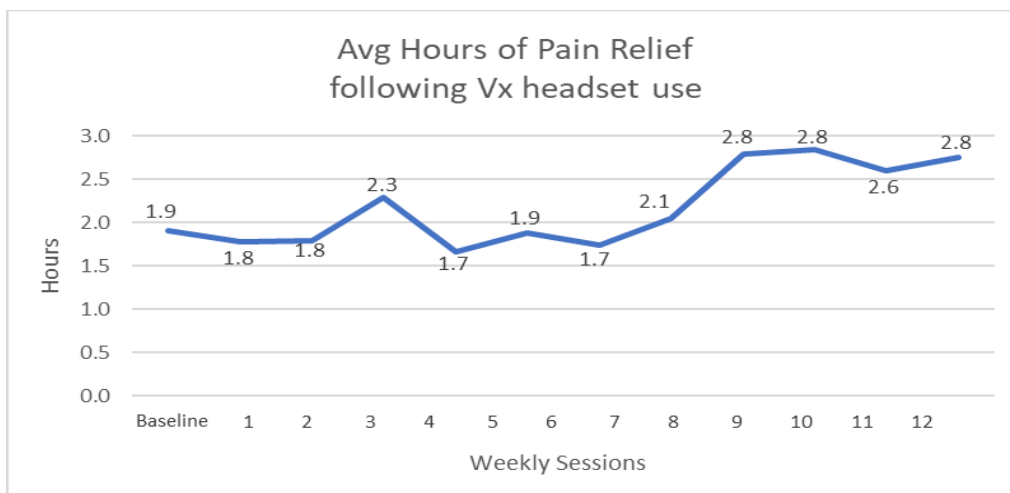
(Graph 1)

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 while using the Vx headset. The patients had immediate results after the initial session. Pain levels were reduced, on average, 40% acutely while the patients were wearing the Vx headset and using the specially selected programs. See Graph 2. Decreased pain levels with the Vx headset use demonstrates the effectiveness of Vx Therapy as an immediate, faster acting analgesic than opioids with equivalent or greater pain reduction and additional benefits without the undesirable side effects.



(Graph 2)

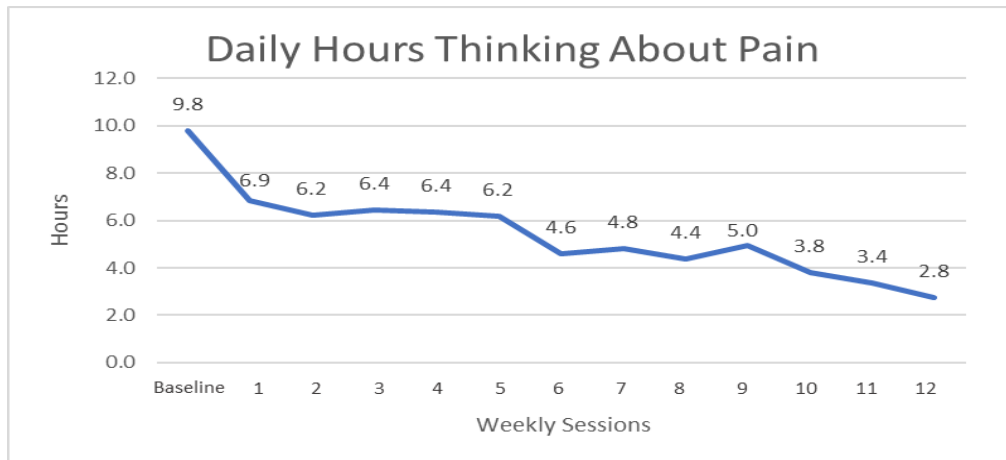
Patients in the Vx Pain Relief Program experienced significant legacy pain relief post Vx headset use. See Graph 3. The patients fell into three categories: those who experienced consistent relief after each session, those whose legacy pain relief increased as sessions progressed and those who had varied results. On average, patients experienced 1.9 hours of legacy pain relief at the start of the program and by the conclusion of the 12-week program, patients were experiencing 2.8 hours of legacy pain relief following Vx headset use. This 47.4% increase in legacy pain relief demonstrates that pain relief is not only maintained over time but increases with additional sessions. This shows the additive effect of neuroplasticity and suggests that patients benefit from longer program duration.



(Graph 3)

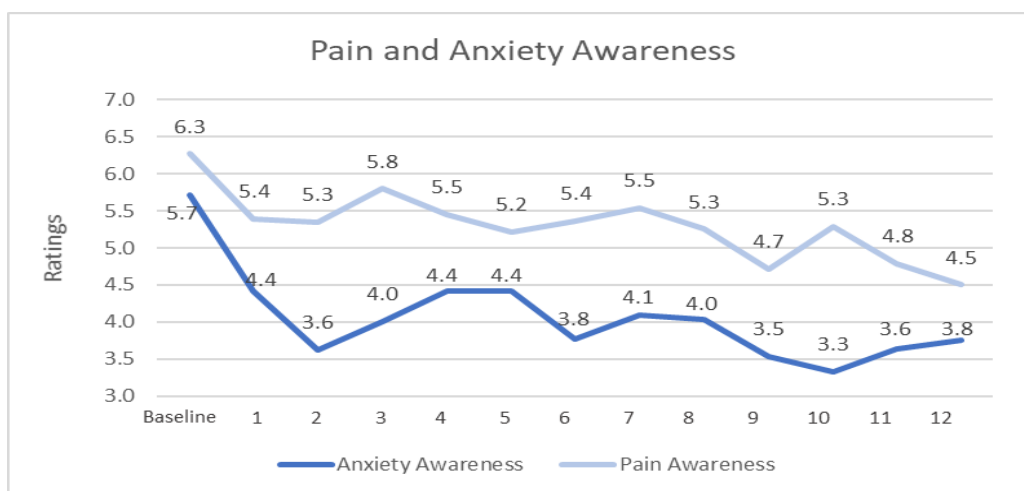
In addition to immediate and legacy pain relief, patients in the Vx Therapy program reduced the average daily time spent thinking about pain from 9.8 hours at the start of the program to 2.8 hours by discharge, or a 71.4% reduction. See Graph 4. This represents a reduction in the

number of hours per day spent thinking about pain. Reduction in time ruminating about pain means reduced risk of pain catastrophization and fear avoidance behaviors which leads to an increased ability to return to work.



(Graph 4)

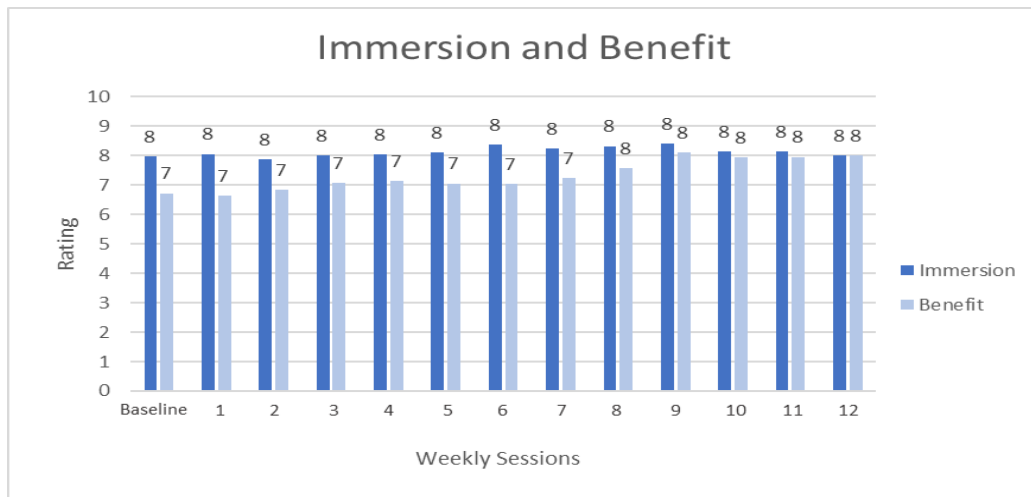
The patients also experienced a reduction in anxiety awareness throughout the program. See Graph 5. At the initial consultation, awareness of pain and anxiety were at the highest level. It is well established that pain and anxiety are strongly correlated. As the patients progressed through the Vx Therapy program they began to manage their pain more effectively and were able to experience pain without a spike in anxiety. Patients in this cohort demonstrated that Vx Therapy actively decreased both pain (28.6% reduction) and anxiety (33.3% reduction) awareness to drive outcomes that allow patients to reintegrate into work and daily life.



(Graph 5)

Patients reported high levels of immersion and perceived benefit throughout the duration of the 12-week program. See Graph 6. This demonstrates that Vx Therapy is capable of not only creating immediate immersion of patients in the Vx experiences, but also sustained

immersion throughout the program. In addition, the patients reported an immediate and sustained benefit utilizing the device. 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 6)

Cohort Report Summary _____

The ability to effectively create a highly immersive environment creates immediate pain relief. It is the immediacy of pain relief that creates the benefit for the patient. The perception of being “high benefit” drives increased patient utilization of the headset and compliance with the telephonic consultations. This compliance is what leads to overall neuroplastic change, chronic pain reduction, pain resiliency, behavior modification and the ability to achieve exceptional outcomes and meet patient centered goals.

Patient Centered Goals _____

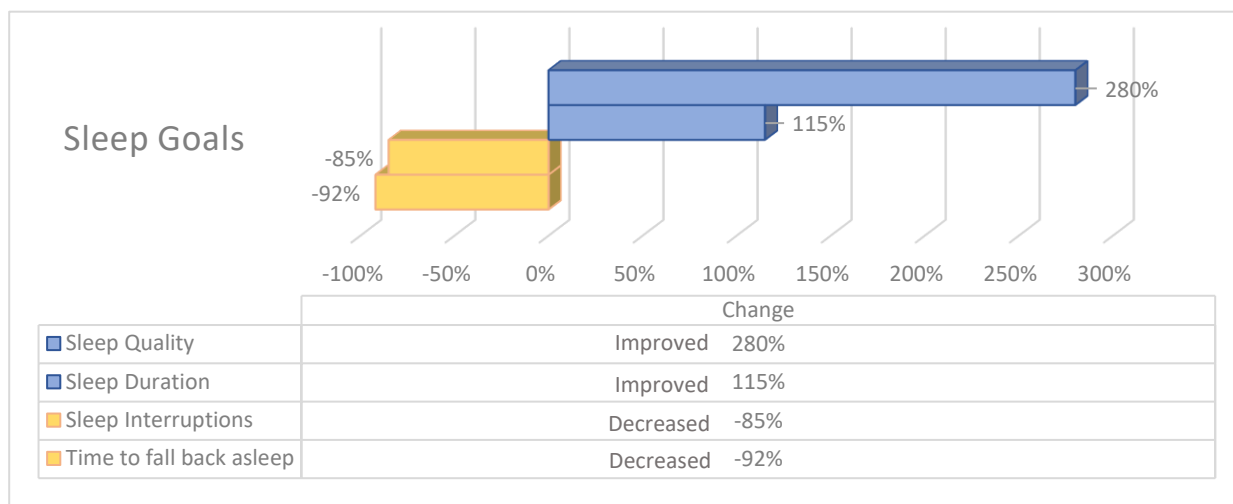
Patients were each asked to set specific goals during the initial consultation. The goals could be pain, sleep, physical, behavioral, or social based. When addressing their specific goals, metrics studied were whether goals were met as well as the percentage of change towards specific goals. Overall, 86% of goals were met or exceeded by patients in the program.

◊ Pain

Patients set specific goals related to their pain patterns and specific pain areas where they would like to see improvement. Patients who set pain goals achieved a 44% decrease in pain specific to their goals. This translates into a greater sense of normalcy which facilitates a willingness to return to work.

◊ Sleep

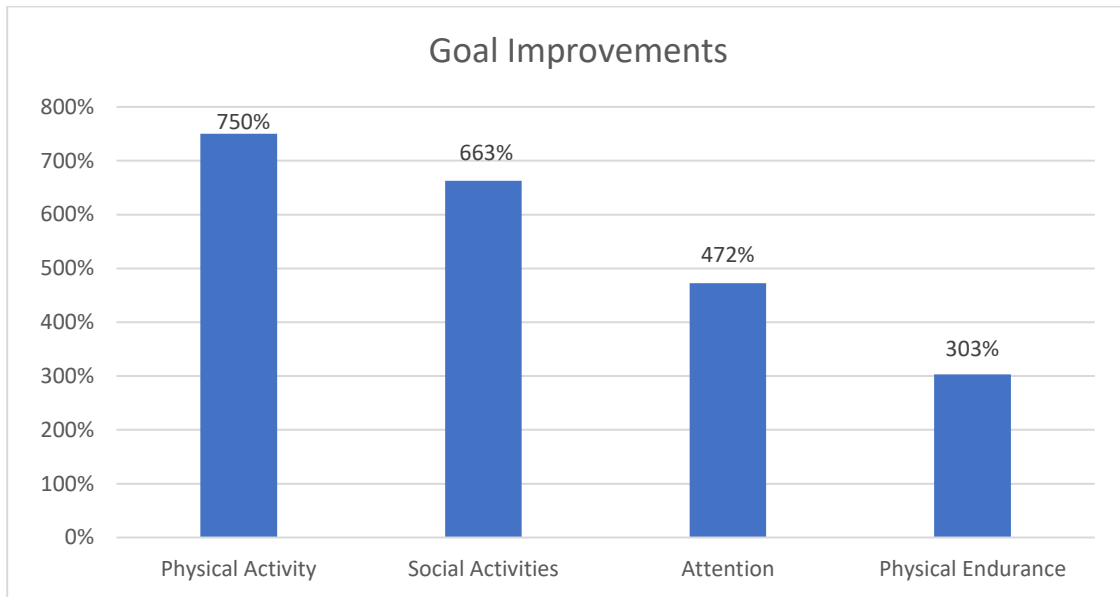
Patients were each asked to set specific goals related to their sleep quality, duration or patterns that if improved, would impact the quality of their day. Enhancing the quality and duration of sleep is critical for positive mental health and physical healing in patients suffering from pain. Patients experienced a 115% increase in the duration of their sleep and a 280% increase in the subjective quality of their sleep. In addition, they reported a decrease of 85% in their sleep interruptions and stated that in the event they did have an interruption to their sleep, they were able to fall back asleep 92% quicker than at the start of the program. See graph 7.



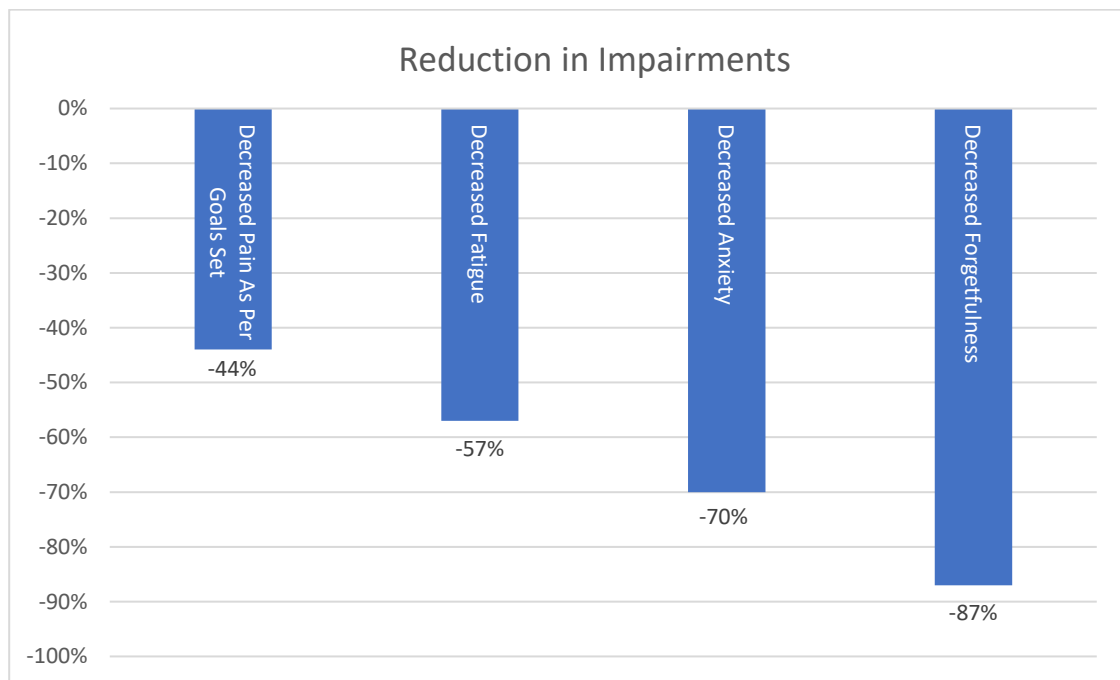
(Graph 7)

◊ Physical Activity

Patients set specific goals related to their physical activity. At the beginning of the program many patients reported difficulty performing physical activities secondary to limitations from pain. At the conclusion of the program, patients reported a 750% increase (See graph 8) in the number of physical activities they were able to perform each week. In addition, patients reported a 303% increase (See graph 8) in the amount of time (duration) they could perform these activities and a 57% decrease (See graph 9) in their fatigue by the completion of the program, which facilitated their increased overall socialization and increased likelihood for return to work.



(Graph 8)



(Graph 9)

◊ Behavioral Activity

Patients also set specific goals related to their behavioral activities within their daily life. Patients often report an inability to perform seemingly basic tasks because of the distractions resulting from pain or from concurrent psychosocial or sleep issues. At the completion of the Vx Therapy program, patients reported a 472% increase (See graph 8) in their ability to focus and complete tasks. To aid in the ability to improve on their behavioral goals, patients reported a 70% decrease (See graph 9) in anxiety which they said increased their ability to engage in their specific behavioral activity goals.

◊ *Social Interactions*

Patients set specific goals related to their socialization and social activities. Prior to initiation of the Vx Therapy, patients reported that their pain and psycho-social co-morbidities significantly inhibited their participation in social activities. At the completion of the program patients reported a 663% increase (See graph 8) in their participation in social activities. Patients reported that their overall sense of well-being and ability to focus on socialization and other pleasurable activities increased during their treatment. Furthermore, they reported an 87% decrease (See graph 9) in their forgetfulness which allowed patients to become more productive in job related tasks. Comfort with social interactions is a good proxy for comfort in a work environment. The ability to resume 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.

Discussion _____

Vx Therapy utilizes a proprietary Vx headset combined with specific behavioral health interventions which allows Harvard MedTech Vx Pain Relief Program patients to become more pain resilient. Patients learned how to manage their pain and anxiety using cognitive behavioral techniques learned from the Vx Therapy program and their behavioral health clinicians instead of fixating on their pain. The ability to manage their pain allowed patients to achieve not only reductions in pain and improvements in sleep profiles, but significant improvement in their physical, behavioral and social goals as well.

Despite the challenges created by unexpected work injuries and unforeseen social and psychological stressors, the Vx Program was able to positively impact many aspects of the patient's life. The Vx headset was delivered to the home and the patient was provided unlimited access to the headset and personal clinician for high levels of engagement and support without adding the additional stress of having to go out to multiple doctors' appointments throughout the program. The Harvard MedTech Vx Therapy program focuses on all aspects of the patient (Biologic, Psychologic, and Social) to treat pain in a holistic manner.

Pain levels were reduced, on average, 40% immediately and concurrently a continuation of pain relief after termination of the Vx Therapy session for 2.8 hours was seen. Patients also reported 28.6% reduction in their awareness of their pain. The immediate and legacy pain relief coupled with the diminished thoughts about pain, creates an environment in which patients can begin to focus on other aspects of their life and how to return to work. From a medical lens this is the Gate Control Theory of pain at work as well a very demonstrable example of active neuroplastic change within the brain. The promotion of neural rewiring

(neuroplasticity) allows for the analgesic benefits of Vx Therapy to become hard wired, as evidenced by the increasing legacy time period of analgesic relief post exposure.

To quantify the effectiveness of pain resiliency with Vx Therapy, we can focus on opiate prescription use. This analysis showed that 69% of patients either eliminated the need for opioid medication (38%) or decreased the amount of opioid medication taken during the program (31%). This ability to minimize pharmacologic interventions provides a resource to avoid continued opiate therapy that has previously not been available to clinicians. Providing a non-pharmacologic option for clinicians that provides both acute and chronic pain relief is demonstratable in the ability of the patient to utilize the Vx headset and achieve almost 3 hours of post treatment analgesia.

The Harvard MedTech Vx Therapy is an effective treatment for patients suffering from pain and associated psycho-social co-morbidities. Promoting pain resiliency and improving the overall emotional state of patients leads to a lower risk of opioid related issues as well as promotes an environment in which patients are significantly more likely to return to work.