RESEARCH ARTICLE

A Pilot Study of At-Home Virtual Reality for Chronic Pain Patients

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Abstract

Chronic pain disorders are a common and expensive health problem worldwide. Available treatments for these disorders have been decreasing and new treatments are needed. Virtual reality (VR) has been used for acute and procedural pain for years but systems are only now becoming available for use with chronic pain. In this study patients with a chronic pain disorder were given the option of using either take-home virtual reality equipment for one month or take-home biofeedback equipment for one month. In the VR condition patients were oriented to the "PainCare" app but could access any free content from the internet as well. Qualitative data was gathered on 23 VR patients and 12 biofeedback patients. Pre-post measures of depression, catastrophizing and function were obtained from 17 VR patients and 8 biofeedback patients. Data found that there was a statistically significant decrease in depression and catastrophizing in the VR group but no such decrease was found in the biofeedback group. No significant increase in function was found in either group though the VR group trended in that direction. One hundred percent (100%) of the patients who tried VR reported that they thought it had helped them overall at least a little. Patient ratings of the VR equipment were more favorable than the biofeedback equipment. This non-randomized small sample study suggests that at-home VR use can be used successfully with patients to decrease the important treatment variables of depression and catastrophizing, and perhaps become a significant contribution to the treatment of chronic pain disorders.

Introduction

Chronic pain is pervasive and costly. In 2011, the Institute of Medicine (IOM) released a landmark report on chronic pain,[1] which estimated that more than 100 million Americans suffer from chronic pain, documenting that pain is a major and significant public health problem. Chronic pain is also a global health problem, causing a significant disability burden for both developed and developing countries.[2] Of 301 acute and chronic diseases and injuries in 188 countries, low back pain ranked first among the top 10 leading causes of years lived with disability and chronic neck pain and migraine ranked fourth and sixth, respectively.

However, despite the ubiquity and cost of chronic pain, treatment options for these conditions have decreased over the past several decades. Multi-disciplinary chronic pain treatment programs, once the primary treatment modality in the treatment of chronic pain, have been on the decline since the late 1990's.[3] Prescription opioids for pain, a treatment which supplanted multi-disciplinary pain treatment as a primary modality in chronic pain treatment, are now also on the decline.[4, 5] Given this situation, multiple authors and agencies have clamored for increased treatments that are effective and accessible for patients with chronic pain.[6, 7, 8]

Virtual reality (VR) equipment has been used successfully in the treatment of acute pain conditions for about two decades, with a multitude of studies showing its effectiveness in acute pain situations such as burn pain and wound care.[9, 10, 11, 12, 13] Two recent reviews of the literature found that while the use of VR for acute pain situations has been fairly well established, more research is still needed on the use of VR for adult chronic pain conditions.[14, 15]

A few studies, including one earlier study at our practice, have investigated the impact of VR on chronic pain while patients are in the office.[16, 17, 18] These studies have shown the effectiveness of VR in reducing chronic pain for patients in the office. These studies have pointed towards VR's likely ability to provide analgesia for chronic pain. The issue then becomes how to deliver VR to chronic patients and what the content of the VR applications should be. Another earlier study by our practice used a small sample of chronic pain patients with neuropathic pain and offered repeated (three) 20-minute VR sessions in the office.[19] The results indicated that repeated sessions in the office, while reducing pain at the time of the sessions, did not significantly reduce pain over the course of a month and did not impact other treatment variables such as depression or catastrophezing.

With the advent of less costly VR devices over the last several years, the option of at-home use of VR has become a more viable option than it was a decade ago. A few investigators have begun to study the use of at-home VR applications for chronic pain. Darnall and others associated with the company AppliedVR conducted a randomized clinical trial of a VR application ("PainEase") for chronic pain. That application was used by patients daily for three weeks and it was compared with an audiotape intervention.[20] Results showed a positive effect for VR on pain intensity, pain

interference with activities, sleep, mood and stress. There was not a significant effect of the VR intervention on catastrophizing or self-efficacy. A subsequent randomized clinical trial by that same group studied the effectiveness of 56-day daily VR program vs a sham VR intervention.[21] This study also showed the effectiveness of the VR intervention on pain intensity, pain interference with activities, sleep, mood and stress, with no significant impact on catastrophizing or self-efficacy.

When treating chronic pain conditions, analgesia is not the only important variable for consideration. Past research has shown that psychological variables are also important in the treatment of chronic pain. One recent review of the literature has found that patients with pain and depression experience reduced physical, mental, and social functioning when compared to patients with only depression or only pain.[22] Another important chronic pain treatment variable is catastrophizing. Pain catastrophizing, which is broadly defined as a tendency to focus excessively on pain and exaggerate its threat value, is considered a key intervention target in psychological therapies for chronic pain, along with pain intensity, physical disability, and mood.[23] Catastrophizing has traditionally been best addressed through multimodal treatment and by pain psychologists who offer cognitive behavioral therapy.[24] However, as noted above, multidisciplinary treatment has been becoming less and less available for chronic pain patients. In addition, there is a documented lack of trained pain psychologists, at least in the United States.[25] Given this situation, the hope is that VR applications can be developed that not only provide analgesia but can also in some way address other key psychological factors such as depression and catastrophizing.

Recent research (above) has compared VR interventions to audiotapes and sham VR (2D nature scenes). This current study compares a VR intervention to the use of another at-home biomedical device: biofeedback. Patients in this study were offered the use of an at-home biofeedback device that measures heart rate variability (HRV). HRV biofeedback has shown promise in the treatment of some chronic pain syndromes.[26, 27] Thus, use of at-home biofeedback using HRV was seen as an appropriate and novel comparison group.

In sum, the aim of this study was to examine the effect of the use of at-home VR on chronic pain patients with a focus on the impact of VR on patient function, depression and catastrophizing. The hypothesis was that at-home VR use would decrease depression and catastrophizing and increase patient overall function, and that these impacts would be greater than in a comparison group using at-home biofeedback equipment. This investigative pilot study had a small sample size and was not randomized but, using data gathered in a clinical chronic pain practice setting, the study could offer important information about the future use of VR in the treatment of chronic pain syndromes.

Methods

Between August of 2019 and December of 2020 chronic pain patients at our practice were offered a one- to two-month trial of an

at-home device, either VR or biofeedback, based on their choice. Flyers were placed around the clinic and patients were informed of this opportunity during medical and psychology sessions at the clinic. Their participation was voluntary and their decision to participate had no impact on their access to any other treatments offered at the clinic. The sessions were free to the patients, were not billed to insurance and were independent of any other psychological therapy. No industry or third-party funds were used in any aspect of this study. While some patients were shown both devices, no patient had a monthly trial of both devices.

The VR choice provided the patient with an Oculus Go headset. At the initial session patients were oriented to the headset and the single hand controller. Patients were specifically oriented to the application "PainCare." This an application created for use by the company AppliedVR and designed for chronic pain patients. It offers some brief education sessions on the nature of chronic pain with emphasis on the importance of learning new behavioral and psychological skills. The application further offers experiences that use the user's breath as a biofeedback mechanism, using the device's microphone to teach self-calming skills. The application also offers various distraction experiences, such as sitting on a sunny beach in Portugal. The PainCare experiences, usually two to three minutes in length, are not sequential and users can access them in any order and use them as often as they desired. In addition to PainCare, patients were instructed on how to access a few other free applications on the headset, such as "National Geographic" (nature videos) and "Wonder land" (various interactive games). Patients were also instructed on how to access the internet using the Oculus Go device through any wi-fi network. From there they could watch movies or YouTube videos if they desired. With this device then patients could access whatever content they desired at whatever rate they desired. They were encouraged to use the VR device regularly but were not given specific prescriptive advice for use and were left to use the device as they saw fit.

The biofeedback choice provided the patient with an at-home biofeedback device made by the company Unyte. This small biofeedback device has a sensor that when attached, either on the ear or on the hand, measures the patient's heart rate and transforms these data into a heart rate variability (HRV) score. The device then used a corded or Bluetooth signal to the patient's phone, tablet or computer. In the initial session a free account for the patient was created on the Unyte website. This allowed the patient to download up to eight "journeys." Journeys are various biofeedback experiences that use the patient's HRV signals to create an interactive experience that encourages increased HRV. For example, one journey uses the HRV signal such that when the patient had increased HRV a cloudy scene becomes increasingly clear, rewarding the patient's success in achieving increased HRV. Aspects of each journey can be tailored to the individual, making it easier or harder to achieve one's goals and varying the visual output to the patient, setting it as he or she would like. Some journeys have audio

coaching and some do not. As with the VR group, patients were encouraged to use the device frequently but were not given prescriptive advice about how often or long to use the biofeedback device.

Patients were given a brief assessment packet before trying either device. This packet contained the nine-item Patient Health Questionnaire (PHQ-9),[28] the Pain Catastrophizing Scale (PCS)[29], and the three-item PEG Scale.[30] At the follow-up visit patients were again given the PHQ-9, the PCS and the PEG. In addition, they were asked to rate their use of their device regarding their pain, their function and general helpfulness of the device. Patients were also offered the opportunity to write any narrative comments about their experience, offering qualitative data about the device. Statistical tests of significance were done in Excel with paired sample t-tests.

A large portion of this study was carried out during the COVID-19 pandemic. This created challenges in obtaining all of the requested data in a timely manner.
Patients were scheduled for one-month follow-up visits, but a few patients possessed their devices for up to three months, as they had trouble making it to the clinic due to pandemic issues (there was no difference in outcomes whether the patient had the device for one month or two). Some dropped their devices off with front door reception staff and did not stay to complete all of the desired assessment tools. So not all patients in the study completed all of the assessment tools. The data collected here were the best that could be obtained given the social situation challenges.

Results

At the end of the study, 23 patients had tried the VR device for at least one month. Qualitative data (post-use comments) were obtained from 22 patients and pre-post quantitative data were obtained from 17 patients. In the comparison group, 12 patients tried the biofeedback device for at least one month. Qualitative data were obtained from 10 patients and pre-post quantitative data were obtained from 8 patients.

Qualitative Data

Table 1 offers a tally of comments provided by patients in free narrative feedback, combined into some categories. The top section of the table summarizes comments related to helpfulness of the device. The middle section tallies comments about possible purchase and the third section tallies comments about types of problems encountered with each device. Of those patients making comments about helpfulness, more patients reported that the VR device was helpful than did those using the biofeedback device. Many more patients said they plan to or already had purchased a VR device for their own use than for the biofeedback device. Fit and comfort was the number one trouble area for VR patients. This was much more of a problem for the VR group than the biofeedback group. Headaches and nausea, side effects found in some past studies on VR, were reported by a few patients.

Table 1: Tally of Comments by Device and Category

VR	BIOFEEDBACK
Helpfulness	
It helped / I liked it = 7	It helped / I liked it = 2
It helped a little = 1	It helped a little = 2
It did not help / I did not like it = 3	It did not help / I did not like it = 2
Purchase	
I went out and bought one = 2	I went out and bought one = 0
I plan to buy one = 1	I plan to buy one = 0
I might buy one = 3	I might buy one = 1
Problems	
Could not get comfortable / Fit issues = 6	Technical Issues = 3
Nausea = 2	Frustrated / Stressed using it = 3
Too fatigued or ill to use it = 2	Headaches = 1
Technical issues = 1	Trouble finding time to use it = 1
Headaches = 1	Could not get comfortable / Fit issues = 1
Trouble finding time to use it = 1	

Table 2: Pre-Post Average Group Scores for the Three Assessment Tools

	VR	Biofeedback
PHQ-9 average score		
Pre	5.9	5.4
Post	3.9*	4.6
PCS average score		
Pre	23.9	23.3
Post	15.7*	21.4
PEG average score		
Pre	21.8	23.3
Post	18.6**	21.4

* = p<.01
** = p>.05

Quantitative Data

The average score for each group was calculated at pre-intervention and at follow-up. A t-test for paired groups was calculated to determine statistical significance of change between the pre and post assessments. Table 2 summarizes these data. A significant decrease in both depression and in catastrophizing was found between pre-intervention and post-intervention for the VR group but not for the biofeedback group. No significant difference between pre and post scores was found for the PEG. A graph of these data is shown in Figures 1-3. The PEG scores trended in the direction of each intervention being helpful but neither change was significant. The PEG is composed of three ratings: **P**ain, interference with **E**njoyment in life, and interference with **G**eneral activity. Each score was later

analyzed separately. All three ratings trended in the direction of helpfulness for the VR condition but no single item reached statistical significance for change.

Figure 1: Pre-Post PHQ-9 Scores

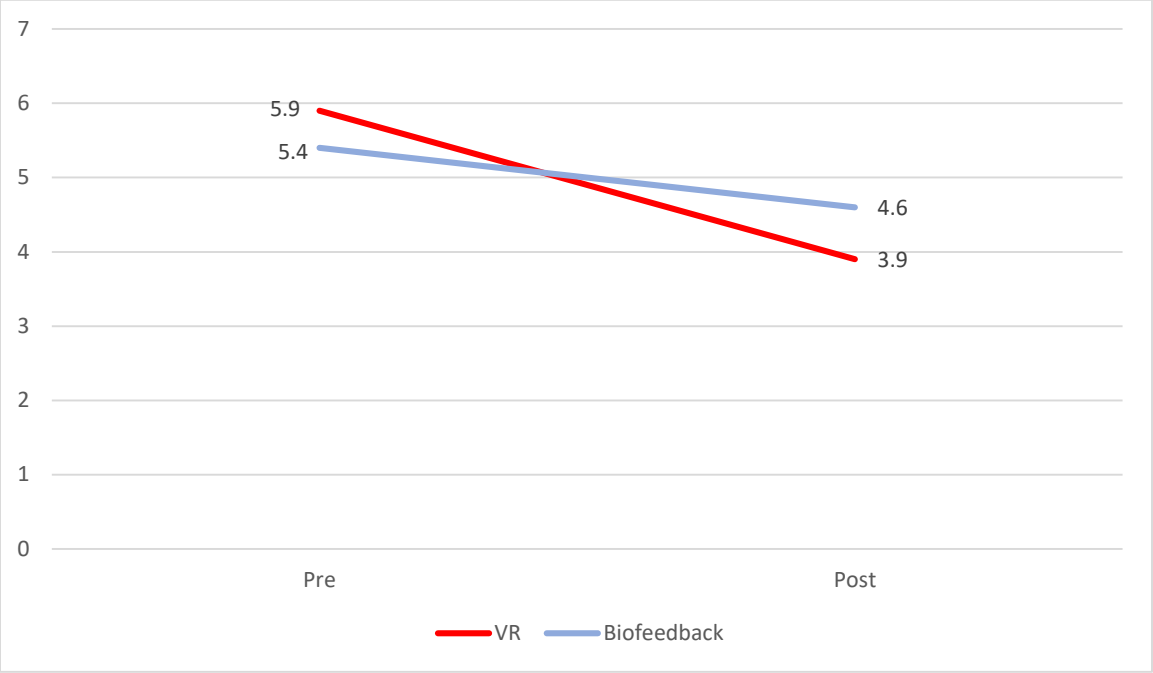
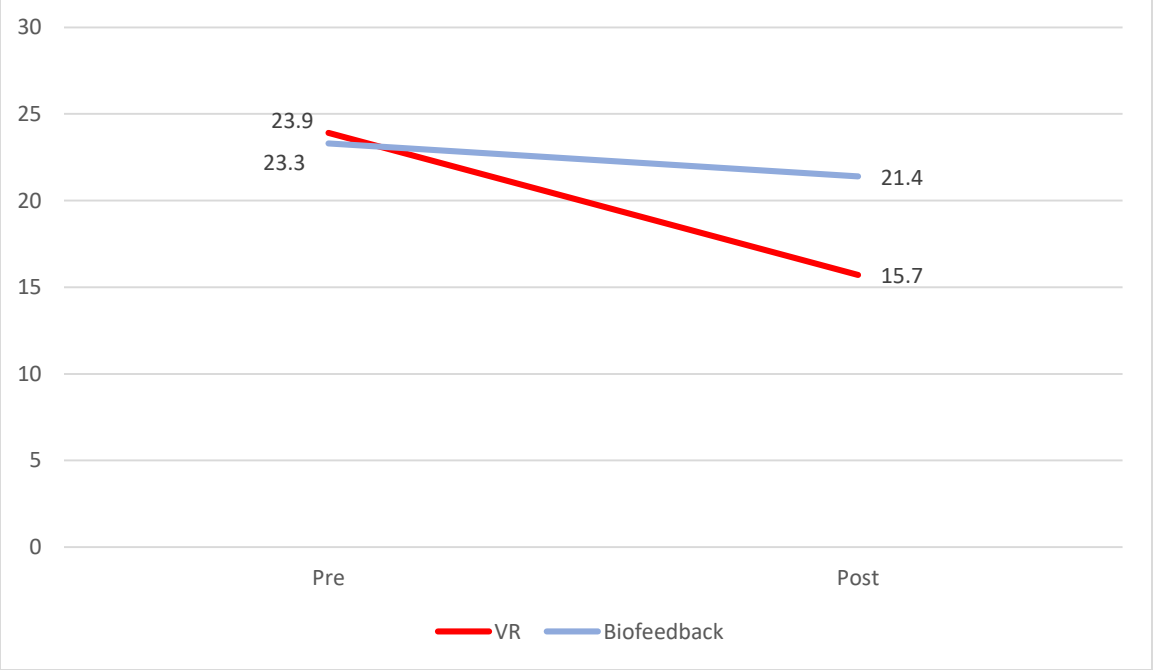


Figure 2: Pre-Post PCS Scores

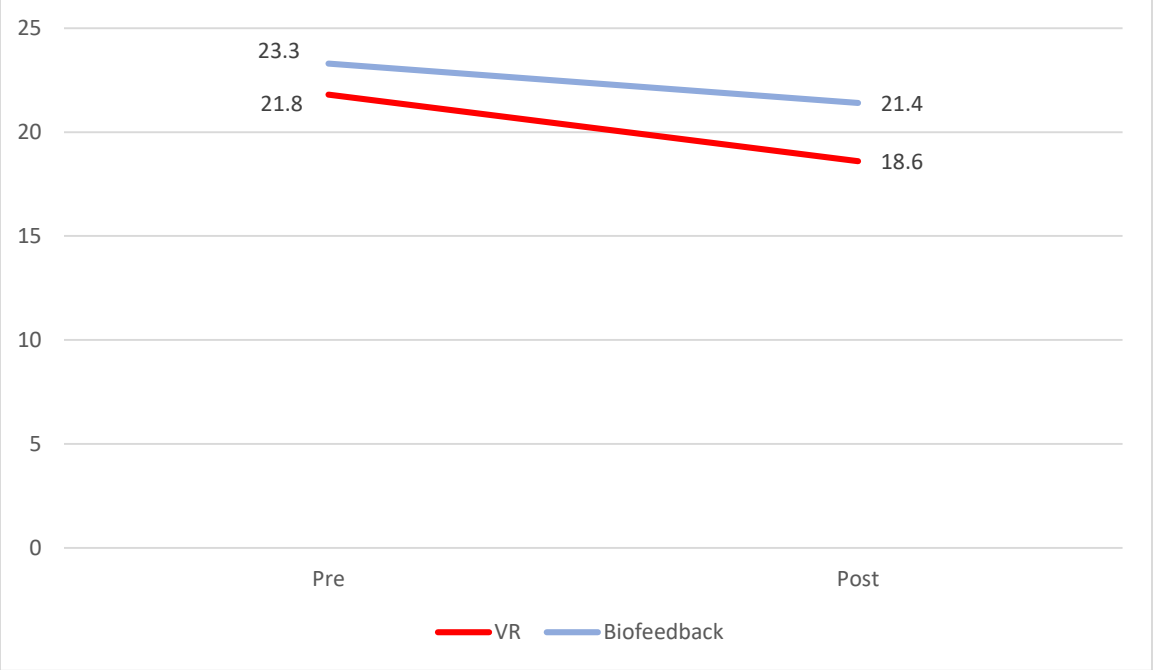


At the follow-up session the patients were given three four-point rating scales. One item asked "Overall, how well would you say this equipment and practice helped you?" with the answers being "No help," "Helped a little," "Helped moderately" and "Helped a great deal." A second item asked "Overall, how well would you say this equipment and practice have helped you **decrease your pain**?" with the answers being "No decrease," "A little decrease," "Moderate decrease" and "Great decrease." A third item asked "Overall, how well would you say this equipment and practice have **increased what you can do**?" with the answers being "No change," "Slight increase," "Moderate increase" and "Great increase." The results of these ratings are presented in Table 3. Results find that 100% of VR patients reported that VR helped them at least a little. More than a third of the VR group reported a moderate to great decrease in their pain, and about a quarter reported a moderate increase in what they could do. The VR group had more favorable ratings than the biofeedback group on all three items: overall help, decrease in pain and increase in function.

Table 3: Four-point Ratings by Each Group on Three Questions

	VR (N=17)		**Biofeedback** (N=8)	
"Overall, how well would you say this equipment and practice helped you?"				
	#	%	#	%
No help	0	0%	2	25%
Helped a little	6	35%	4	50%
Helped moderately	7	41%	1	13%
Helped a great deal	4	24%	1	13%
"Overall, how well would you say this equipment and practice have helped you **decrease your pain**?"				
No decrease	2	12%	4	50%
A little decrease	9	53%	3	38%
Moderate decrease	5	29%	1	13%
Great decrease	1	6%	0	0%
"Overall, how well would you say this equipment and practice have **increased what you can do**?"				
No change	5	29%	6	75%
Slight increase	8	47%	1	13%
Moderate increase	4	24%	1	13%
Great increase	0	0%	0	0%

Figure 3: Pre-Post PEG Scores



Conclusions and Discussion

In this small non-randomized pilot study of the use of at-home VR for chronic pain patients, the data points to the finding that at-home VR use can be effective for chronic pain. The use of VR for at least one month was associated with statistically significant decreases in depression and in catastrophizing as measured on the PHQ-9 and the PCS. A statistically significant increase in function was not found here using the PEG, though the data did trend in the hoped-for direction. About 70% patients using VR indicated that they thought it had helped increase what they could do at least slightly, based on a question using a four-point rating scale. One hundred percent of patients in the VR group reported that they thought VR had helped them at least a little. Significant decreases in depression and catastrophizing were not found in a smaller comparison group who used an at-home biofeedback device, and patient ratings were not as positive about the biofeedback device as in the VR group. Comfort and fit issues were clearly the most common complaint about the use of VR based on qualitative comment data. There were some complaints about nausea, headaches and technical issues but they were not common in the VR group.

There are caveats to these data and this study. As noted, it was not a randomized control study and the sample size was small. It was surprising that more patients did not take the opportunity to try a VR headset (or biofeedback) for at least one month for free. We enrolled only 34 total patients over a 16-month period at a fairly large pain practice (about 1200 active patients). While the COVID-19 pandemic was present through most of this study, the clinic still saw most of its patients in the office using strict infection control procedures during this time so

patients were exposed to the advertising about the study either through a flyer or a brief in-person mention by a psychologist during a psychology visit. When discussing the possible use of VR with patients in person during psychology session, most patients seemed uninterested and were much more focused on pharmacological treatment of their pain. It would appear that patients are not naturally impressed with the value of VR and future clinicians will have to invest significantly in patient recruitment and "selling" the idea of at-home VR use to chronic pain patients.

Patients in this study were not randomized to the two devices offered. A larger randomized control trial would offer more definitive data about the comparison of at-home VR versus at-home biofeedback. In this exploratory study in a clinical setting, there was some data loss from patients and a few patients had a longer time of use than others. It did not appear that longer or shorter use had any impact on outcomes based on a subjective analysis of the data obtained, but a tighter research protocol would offer more definitive answers on this question.

It is noted that this study found a statistically significant improvement in catastrophizing while two past studies by the AppliedVR group using a similar VR application did not achieve this finding. That group had patients use VR daily in a series of sequential experiences over a 21-day and then a 56-day period. Rather than concluding that this study's VR intervention was in some way superior to the AppliedVR group; that is, allowing "free range use" might be more effective than a structured program of experiences or that PainCare is more effective than PainEase, another hypothesis is proposed here. The AppliedVR group, for the sake of brevity and patient burden, used a four-point catastrophizing scale rather than the original 13-item PCS. It is hypothesized here that the use of this four-point scale restricted the range of catastrophizing scores and inhibited a statistically significant finding of change. Here the original 13-item PCS was used and a statistically significant change in catastrophizing was found. More research is needed on this issue, as being able to significantly decrease patient catastrophizing is an important consideration for any VR application in the treatment of chronic pain.

The design of this study allowed patients to use the VR device as often as they desired and gave no prescriptive advice for its use beyond encouragement to use it "often." Additionally, patients were allowed to use VR in whatever way they desired. They were pointed to the specific application "PainCare" which is specifically designed to help chronic pain patients through education, skill teaching and distraction and offers a biofeedback component using the patient's breath. However, pain patients could access the experiences in whatever order they wanted and use as many or as few as they desired. In this study patients also had the ability to access whatever applications they desired (as long as they were free) and browse whatever content they desired from the internet. This "free range" use allowed patients the ability to use VR in a wide range of ways, individualized for each patient's

needs and desires. One particular example was one male patient in his thirties with a neuropathic pain condition. He enthusiastically took to the use of VR. At the end of the month trial he returned the loaned equipment and said he already purchased a new VR system of his own. He said he found the relaxing experiences of the PainCare application only slightly helpful. On the other hand, he found that deeply immersive interactive games offered the most analgesia, so he bought a system with dual hand controllers which he used to play a sword fighting game. At our follow-up visit he said that when he had severe pain, particularly at night, he would get up and engage in virtual sword fighting in his living room until his pain subsided and then he could get back to sleep. He said that VR was the most helpful pain treatment intervention he had been offered at the clinic and it had become his primary tool in dealing with his chronic neuropathic pain. This is a case of a patient finding the right VR application for his personality and pain condition.

This study studied the use of VR in only the broadest terms with patients using the loaned device in whatever way they desired. This study indicates that VR seems to be effective on the whole but it is unknown exactly what VR applications and experiences are most helpful and what "dose" of VR is required for a clinically significant effect. It is likely that individualizing the VR experience for each patient, as in the example described above, will be the ultimate clinical pathway for VR, rather than trying to develop a "one size fits all" single application for chronic pain. The clinical issue will be to find ways to assess patients on the front end and determine which applications and experiences will likely be most helpful for each individual patient. The results of this study indicate that VR, when offered in the broadest way possible in a clinical pain practice setting, seems effective in helping patients with their chronic pain and with the other important treatment variables of depression and catastrophizing. Based on the results of this study, when coupled with the results of other recent studies, it would appear that at-home VR will soon be an important and hopefully common clinical tool in the treatment of chronic pain conditions.

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