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Original Article

The use of virtual reality for Peri-procedural pain and anxiety at an outpatient spine clinic injection visit: an exploratory controlled randomized trial

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Abstract: Chronic pain is a major public health problem. There is a need to develop novel treatment strategies to address this growing issue. Virtual reality is emerging as an alternative approach to help people suffering from chronic pain. The purpose of this work was to explore the feasibility, acceptability, and impact of a brief virtual reality relaxation video on peri-procedural pain and anxiety in chronic low back pain patients receiving spinal injections. The intervention was delivered in the context of a busy fluoroscopy injection clinic. Upon arrival to the clinic, consented patients were randomized into one of three groups: (1) Audiovisual monitor-flat screen (AV) (2) Virtual Reality headset (VR) and (3) Control-no intervention. The main questions we set out to answer were: (1) Is it feasible to deliver the intervention in the context of clinical care? (2) Was the intervention acceptable to patients? and (3) Did the intervention impact pain and anxiety surrounding the injection procedure? Viewing a brief relaxation nature video in AV or VR format was not associated with statistically lower pain scores following an injection procedure compared to controls. However, the intervention was associated with lower anxiety scores recorded prior to the injection compared to controls. Importantly, the virtual reality intervention was acceptable and feasible to integrate into a clinic setting, however, to maximize effectiveness, the content delivered to this population should be targeted and delivered over a longer duration. In addition, alternative outcomes and settings beyond peri-procedural pain surrounding an injection should be explored.

Keywords: Chronic low back pain, virtual reality, pain management, procedural pain, procedural anxiety

Introduction

The management of chronic pain is a significant public health issue related to escalating treatment costs, lost productivity, disability and medication use. The prevalence of chronic pain is rising alarmingly across all subpopulations, with chronic low back pain (LBP) being labeled as one of the 15 most expensive medical conditions [1]. Chronic LBP conditions can develop into complex pathological states involving biopsychosocial components that are often non-responsive to traditional medical interventions [2, 3]. Novel treatment strategies need to be explored to address this growing healthcare concern. There is emerging evidence that virtual reality (VR) may be an effective medium for delivery of pain distraction in experimental and clinical settings among various patient populations and ages [4-10]. However, less is known about the use of this technology in the context of care delivered in an outpatient clinical setting in patients with chronic LBP receiving spinal injections. To explore the use of this technology, a 5-minute nature relaxation video was delivered in a computer flat-screen audiovisual format (AV) and a virtual reality format (VR) to chronic LBP patients presenting for a spinal injection. Our aims were: (1) to determine the acceptance of and interest in the nature relaxation video delivered in either format, (2) to determine the feasibility of delivery of this type of intervention in the context of a busy spine and pain management clinic, and (3) to compare the AV and VR groups to controls on peri-procedural pain and anxiety pre/post spinal injection.

Materials and methods

Prior to initiation of any study procedures, the study was registered at clinicialtrials.gov (Clinical Trials Identifier: NCT03819907) and was approved by the Partners Human Research Committee (PHRC) which is the Institutional Review Board (IRB) of Partners HealthCare and conducted in accordance with the Declaration of the World Medical Association.

Subjects

Patients were recruited from the medical practice of the principle investigator who screened the patients for inclusion/exclusion criteria during their scheduled clinic visit. During the clinic visit, the physician conducted a thorough examination and review of the medical history, including available images. Once it was determined that a spinal injection was a possible interventional strategy, those patients were considered for recruitment. Inclusion criteria: 1) patients electing to receive a lumbar spinal injection and 2) patients meeting the definition of chronic LBP as established by the NIH task force [11]- back pain that has persisted at least 3 months, and has resulted in pain on at least half the days in the past 6 months. The etiology of LBP was not considered as recruitment criteria. Exclusion criteria: 1) age younger than 18 years 2) not being fluent and literate in English. Informed consent was obtained prior to participation in any study procedures. Written informed consent was obtained from 60 patients meeting inclusion criteria. The consort flow diagram (**Figure 1**) outlines the flow of patients from screening to study completion.

Upon arrival at the injection visit, consented patients were randomized into one of three groups: Control, AV, or VR. The sample size of 45 (15 in each group) was calculated using the minimally clinical importance difference of our main outcome, the numeric pain scale [12]. A printed computer-generated randomization table was used ensuring 15 patients in each group.

Usual clinic procedures were adhered to for all groups and included the collection of PROMIS® questionnaires (Patient-reported Outcomes Measurement Information System) addressing global health (physical and mental), physical function, pain intensity, pain interference, depression and anxiety [13]. All consented patients were then given a battery of questions recommended by the NIH task force on chronic LBP [11] and the Modified Oswestry Disability Index (MODI) [14]. The outcome measures of the numeric pain scale [12, 15] (0-no pain to 10-worst possible pain) and the anxiety thermometer [16] (0-not at all anxious to 10-extremely anxious) were administered to all groups pre-injection (two time points) and post-injection (at the conclusion of all standard clinic procedures). The typical time interval of pre/post outcome data collection was 45 minutes to 1 hour.

All consented patients received the spinal injection using the standard protocol for the clinic and completed the additional study questionnaires and pain/anxiety outcome measures pre-injection (two time points) and post-injection. Patients randomized into the control group received no intervention while they waited for the injection procedure. Prior to the injection procedure, patients randomized into the AV group viewed a five-minute nature relaxation video by ECOVR (a non-profit initiative that develops immersive nature content) on a desktop computer flat-screen monitor. Patients randomized into the VR group viewed the same content in VR immersive format in the Oculus GoÒ headset. Patients randomized into the control group received no intervention. To assess tolerance to the virtual reality exposure, the virtual reality symptom questionnaire [17] was given to those patients randomized into the VR group. In addition, the AV and VR patients were asked if they would be interested in viewing the content at home and if they felt the nature relaxation content would be useful in helping them manage their chronic pain.

Statistical analysis

STATA (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP) was used for data analysis. All data was tested for normality using the Shapiro-Wilk test. A one-way analysis of variance (ANOVA) using pain and anxiety change scores was used to check for statistically significant differences between the three groups. Bartlett's test was calculated to assess equal variances between groups. Pearson r correlation coefficients were calculated between: (1) the percent MODI score and the PROMIS® physical

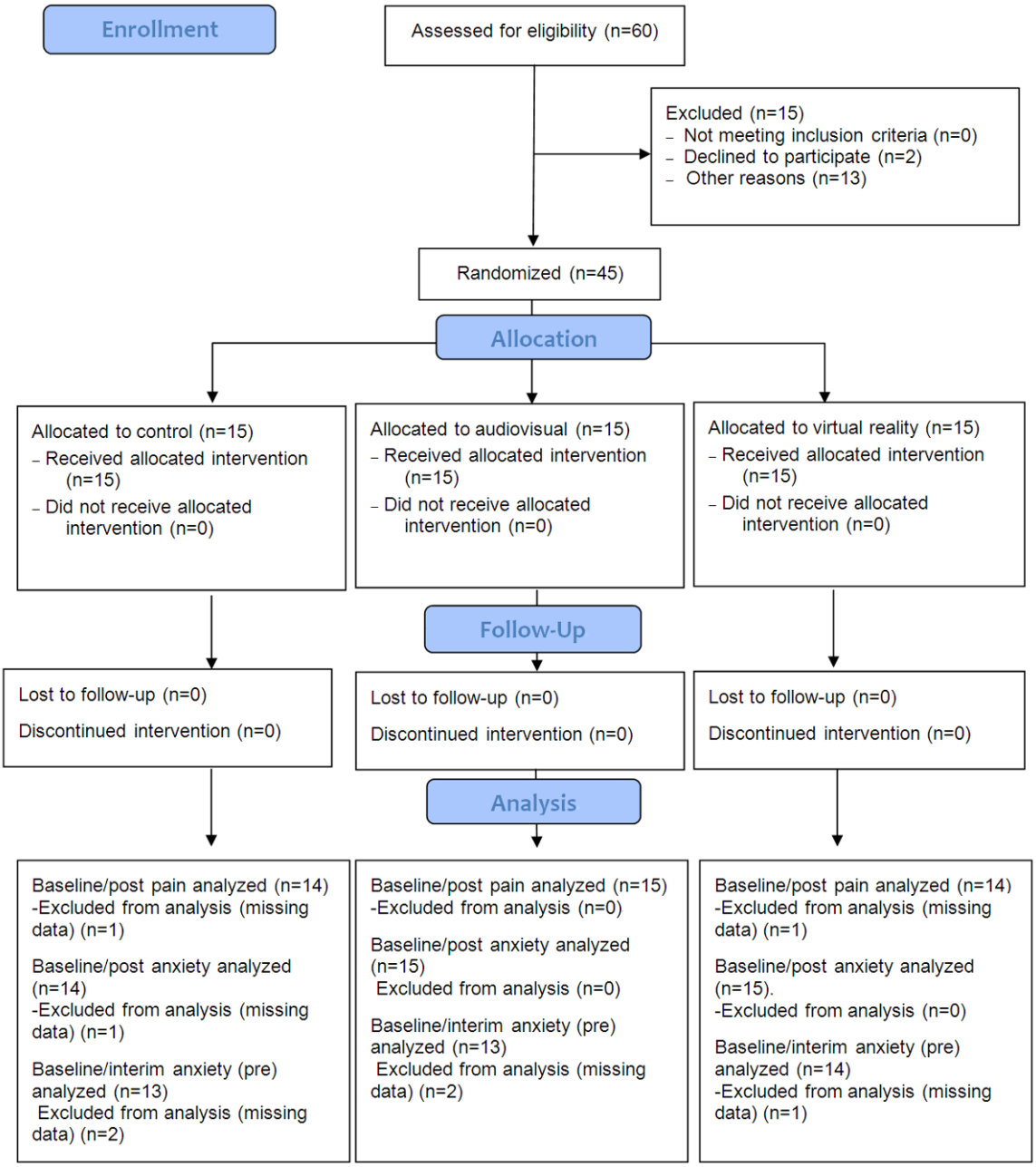

Figure 1. CONSORT flow diagram-outlines the flow of study patient from screening to study completion.

function score and (2) the PROMIS® anxiety score (an average of the past 7 days) and the baseline anxiety score measured by the anxiety thermometer.

Results

There were no adverse events. There were statistically significant differences at baseline (**Table 1**) in body mass index (BMI) between the control and AV groups with the control group mean BMI being greater. The baseline numeric pain rating (NPR) scores were statistically different at baseline between the control and the VR group with the VR mean baseline pain score being lower.

All analyzed variables were normally distributed. There were statistically significant differences at baseline between the control and VR groups in physical function (VR group had better physical function on average), global health

Table 1. Baseline characteristics with *P* values for significant group differences

Characteristics	N	Mean ± SD or N (%)	*P* = significant diff between groups (A/B), (A/C), (B/C)
Age (Y)	45	61.9 ± 17.7	
% Female	45	27 (60)	
BMI, kg/m^2	45	28.0 ± 5.4	*P* = .04 between A/B
Ethnicity	45		
Hispanic or Latino		3 (6.7)	
Race	45		
% White		36 (80)	
% Black		4 (8.9)	
% Other/not reported		5 (11.1)	
Average 7-day pain**	42	6.0 ± 1.8	
Baseline pain: NPRS 0-10	45	5.0 ± 2.3	*P* = .009 between A/C
Baseline anxiety thermometer: 0-10	45	2.9 ± 2.6	
Chronicity*	45		
3-6 months		3 (6.7)	
6-12 months		6 (13.3)	
1-5 years		19 (42.2)	
>5 years		17 (37.8)	
Frequency of LBP*	45		
Every day/nearly every day in past 6 months		32 (71.1)	
At least half the days in the past 6 months		10 (22.2)	
Less than half the days in the past 6 months		3 (6.7)	
Radiating leg pain in past 2 weeks	44	31 (70.5)	
Hx of lumbar surgery	45	6 (13.3)	
Hx of Opioid use for pain	44	15 (34.1)	
Hx Prior injections	38	29 (76.3)	
Injection procedure performed	45		
Interlaminar epidural steroid injection		24 (53%)	
Facet joint injection		11 (24%)	
Transforaminal epidural steroid injection		4 (9%)	
Medial branch block		4 (9%)	
Sacroiliac joint injection		2 (5%)	
PROMIS® scores			
Physical Function SF 10a**	43	38.9 ± 7.6	*P* = .05 between A/C
Global health	42	40.8 ± 8.0	*P* = .03 between A/C
Global health mental	42	49.5 ± 10.7	
Pain intensity**	42	54.5 ± 5.8	*P* = .02 between A/C
Pain interference**	42	62.0 ± 7.0	*P* = .04 between A/C
Depression	42	49.6 ± 9.4	
Anxiety	42	49.7 ± 9.7	
Modified Oswestry Disability Index	42	35.3 ± 17.7	

BMI = Body Mass Index. LBP = Low back pain. NPRS = Numeric Pain Rating Scale: 0-10; 0 = no pain; 10 = worst possible pain. Anxiety thermometer: 0-10; 0 = not at all anxious; 10 = extremely anxious. PROMIS® = Patient-Reported Outcomes Measurement. Information System-T-scores in a relevant reference population with a mean of 50 and SD of 10; higher scores reflect more of an attribute which could be desirable or undesirable, depending on the concept being measured, A = Control; B = Audiovisual (AV); C = Virtual Reality (VR). *NIH Task force criteria for describing chronic low back pain. **NIH Task force criteria for stratifying chronic low back pain by impact.

Table 2. Acceptability of the audiovisual and virtual reality interventions

	n	yes	no	unsure
Would you be interested in having the AV content to view on your computer at home?	13	54%	46%	
Do you feel this type of content (AV) might be useful in helping you manage your pain?	13	46%	23%	23%
Would you be interested in having the VR content to view on a headset at home?	15	27%	60%	13%
Do you feel this type of content (VR) might be useful in helping you manage your pain?	15	27%	33%	40%

Table 3. Virtual reality symptom questionnaire

	N	None = n (%)	Slight = n	Moderate = n	Severe = n
General Body Systems					
General Discomfort	15	12 (80)	2	1	0
Fatigue	15	14 (93)		1	0
Boredom	15	14 (93)		1	0
Drowsiness	14	13 (93)		1	0
Headache	15	15 (100)			0
Dizziness	15	14 (93)	1		0
Difficulty Concentrating	15	15 (100)			0
Nausea	15	15 (100)			0
Eye Related Symptoms					
Tired eyes	14	14 (100)			0
Sore/aching eyes	14	14 (100)			0
Eye strain	13	12 (92)		1	0
Blurred vision	15	10 (67)	3	2	0
Difficult focusing	15	13 (87)	1	1	0

(VR group had better global health), pain intensity (VR group had lower pain intensity), and pain interference (VR group had lower pain interference scores). All variances were equal between groups. Pre-injection anxiety levels were lower than anticipated. Years of pain duration was relatively high in this population with 80% reporting years of pain from 1 to greater than 5 years and 70% reporting pain every day or nearly every day in the past 6 months. Of the 38 patients answering the question, 76% reported they had received a prior injection. On average, physical function scores were 1 SD below the mean T score of 50. There was a strong correlation (r = .79) between the percent MODI score and the PROMIS® physical function score. There was a moderate correlation (r = .53) between the PROMIS® anxiety score (an average of the past 7 days) and the current anxiety score measured by the anxiety thermometer.

In the AV group, 54% indicated interest in having the content to view at home, however, 60% of patients did not express interest in the VR content for home viewing (**Table 2**). Viewing the content in the VR headset did not result in any appreciable negative symptoms (**Table 3**). Nine patients who viewed the content in the VR headset entered qualitative comments (**Table 4**) with a range of experiences noted. Several older adults entered positive comments, with the youngest patient reporting the most negative comments.

Results of a one-way ANOVA did not reveal a statistically significant difference between the three groups in the baseline/post injection pain change scores or the anxiety change scores (**Figure 2**) with variances being equal between groups. Mean baseline/post injection pain scores declined the most in the Control and AV groups and the least in the VR group. In the one-way ANOVA using anxiety change scores, mean baseline/post injection anxiety declined the least in the control group followed by the VR group with the greatest mean change in the AV group.

Results of a one-way ANOVA were significant (P = .003) using baseline/interim (pre-injection) anxiety change scores (**Figure 3**). Variances were equal between the three groups. A Bonferroni analysis revealed the significance was between the control and the audiovisual group (P = .002). The variances in the baseline/interim pain change scores were unequal between groups, violating the assumptions of a one-way ANOVA using these change scores.

Results of a one-way between-group ANOVA were non-significant (P = .50) using interim and post anxiety change scores. Variances were equal between groups.

Discussion

The major findings of our exploratory trial were that integrating the five-minute nature relax-

Table 4. Patient characteristics and qualitive comments from the virtual reality randomized patients who entered additional comments (n = 9)

Age/gender	*Anxiety	Qualitative comments
24/female	2	"One scene made me feel a bit terrified because of height. It is the one where the viewer stands on top of a snow-capped mountain, overlooking some cool red/brown rock formation."
70/female	0	"Very positive experience. Served as a good distraction beforehand. Not sure how effective it could be for pain, but would try it. This is wonderful."
65/female	5	"Without my glasses, had to squint to see, more bothersome to be honest. Maybe if I could wear my glasses it would have been helpful."
53/male	2	"Good experience. Recognized some of the places in the nature video."
70/female	3	"Thought the kangaroo that came out of the left field of vision was a rat."
74/male	0	"Pleasant experience, but I feel that kindness, consideration and respect can go a long way toward decreasing anxiety surrounding medical procedures and appointments."
75/female	0	"I wish I had one of these for home. Very relaxing. Blurred vision toward the end."
71/male	1	"So relaxing I fell asleep. Thank you."
77/female	0	"It was relaxing and beautiful!"

*Baseline Anxiety as measured by the anxiety thermometer (0-not at all anxious to 10-extremely anxious).

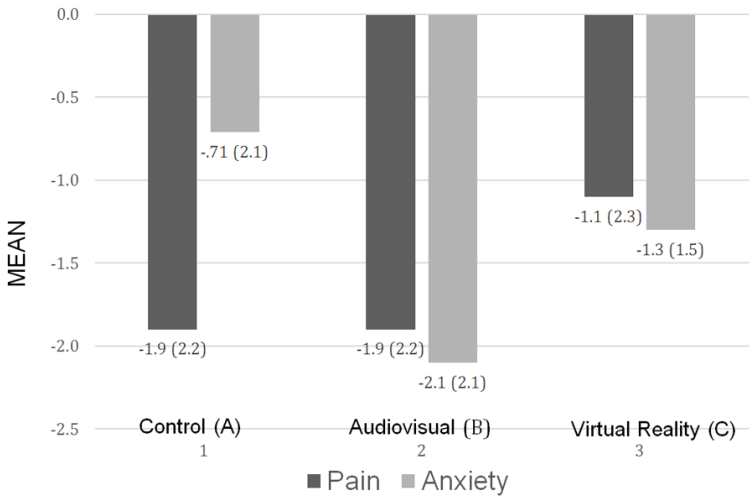

Figure 2. Mean Pain and Anxiety change scores baseline/post injection*-Mean (SD); Between-group One-way Analysis of Variance (ANOVA); Pain: P = .56; Anxiety: P = .18. *The numeric pain rating and anxiety scores were collected at three time points, two taken prior to the injection: (1) baseline, (2) interim-immediately after viewing the VR or AV content; in the case of the control group, there was no intervention delivered, and (3) post-injection: after standard clinic procedures had been completed. This analysis was performed using the baseline and post injection time point measurements.

ation video via computer flat screen (AV) or via a virtual reality (VR) headset was feasible in a busy fluoroscopy injection clinic and generally acceptable in this patient population. Many older adults reported positive experiences with the VR headset suggesting that age may not be an important factor when considering who might benefit from VR. There was less interest in having the VR content for home viewing compared to the flat screen content. This could be explained due to the prevalence of home flat-screens (smart phones, tablets, and computer monitors) compared to home VR headsets. The AV group was generally more receptive to the content than the VR group, possibly explained by the novelty of the VR technology. Regarding the feasibility of implementing the use of relaxation content (AV or VR delivered) in a fluoroscopy clinic, four consented patients were missed (8%) at the injection visit due to determination by clinical staff that performing the study procedures would interfere with clinic work flow. Interventions delivered in the context of clinical care need to be carefully coordinated with clinical staff to optimize both clinic and study procedures. Viewing the VR content was comfortable and did not produce any appreciable negative symptoms.

One factor that may have contributed to the lack of effectiveness of the VR intervention on pain when compared to controls is that patients in this group started with statistically significantly lower baseline pain scores compared with the control group (P = .009), leaving less room for improvement from baseline. Also,

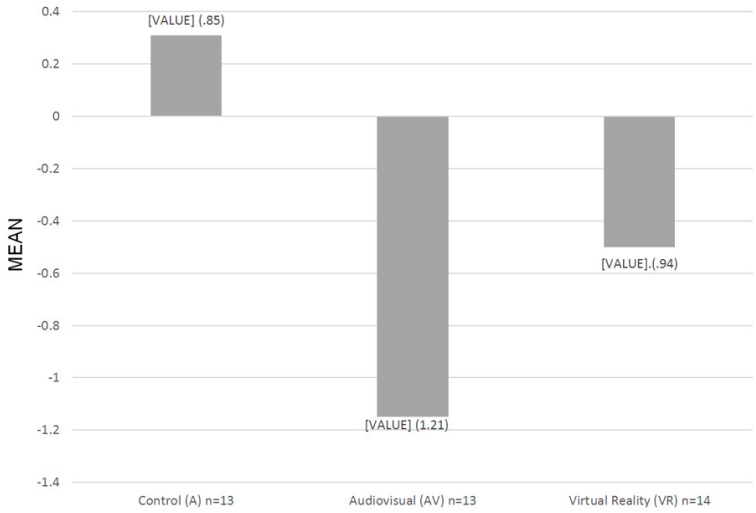

Figure 3. Mean Anxiety change scores baseline/interim*-Mean (SD). *The interim anxiety score was collected right before the patient was moved from the preparation room to the injection suite-after viewing the relaxation video in the AV and VR groups. No intervention was delivered to the control group. Approximately 20-30 minutes elapsed between baseline and interim data collection.

within-subject variability was high, making it more challenging to achieve statistically significant differences between groups. Additionally, the AV and VR interventions were designed to impact an expected transient elevation in pain surrounding the injection procedure, which did not occur. In this study population, there were immediate improvements in post-injection pain reported by patients in the control group. This immediate response could have resulted from local anesthetic administration or other unidentified factors. Given this unexpected immediate post-injection decline in pain, it is possible that the relaxation intervention was not robust enough to add to this response and that future trials should be designed to explore longer term pain, anxiety and function in this complex patient population.

Using change scores measured at baseline and immediately after viewing the AV/VR content (pre-injection), we observed an anticipated elevation in anxiety in the control group compared to a decline in the AV and VR groups. However, this statistically significant difference between the control and AV groups disappeared by the post-injection measurement time point. Unexpectedly, the correlation between baseline anxiety and pain was low (r = .18), possibly due to the complexity of this chronic pain population in the unique context of an injection procedure. The AV and VR groups did report greater declines in anxiety compared to controls following the injection procedure, but these differences did not reach statistical significance. While the variances were equal in the groups, within-subject variability was high, making it harder to reach statistical significance between groups. Pre-injection anxiety levels were unexpectedly low. This could partially be explained by the fact that 76% of these patients had received previous injections, possibly contributing to a level of comfort with the procedure and known expectations. Also, it is possible that anxiety levels would decline immediately following the procedure simply because the procedure is over. The anxiety thermometer was moderately correlated (r = .53) with the PROMIS® anxiety score and is user friendly. This tool should be further studied to explore its psychometrics and MCID in a chronic pain population.

The impact and chronicity of pain in this study population was moderate to high. These factors can contribute to the complexity of pain and the likelihood that there may be multiple biopsychosocial determinants of pain responses, making the potential impact of this brief five-minute nature relaxation intervention more muted. Alternative content should be explored, developed, and studied for optimal effectiveness in this patient population. The content should be specifically targeted for longer term impact on pain management, reducing the need for expensive, invasive medical procedures and addictive drugs. Additionally, during delivery of the VR content via a headset, patients were seated to optimize safety. Sitting is often identified as an uncomfortable position in patients with LBP. In this study population, 50% of the patients in the VR group identified sitting as a challenging position. This could have interfered with the effectiveness of the VR content. Alternative positions for VR content delivery should be explored to optimize effectiveness.

Study limitations

Assignment of group was not blinded to the patient or research staff. This introduces the potential for observation and/or reporting bias, which is an important concern in experimental study designs.

Integrating this intervention into a busy clinical practice necessitated streamlining the data collection tools to minimize respondent burden and reduce interference with clinic procedures. A compromise was made between using instruments with better psychometrics and those with streamlined clinical utility. An example is the use of the anxiety thermometer that has not been as extensively studied compared with other tools for measuring anxiety.

While the use of the numeric pain rating scale is common, there are obvious limitations in using this tool to measure pain, especially in this complex chronic pain population. Even though numeric pain rating scores are analyzed as continuous, the intervals between pain rating scores on the scale may not, in fact be equal. The difference between a pain rating of 10 and 8 may be perceived differently than the difference between a 3 and a 1 at the lower end of the scale. A patient at a higher pain level may interpret a change more dramatically than a patient experiencing a lower level of baseline pain.

Lastly, missing data is always a threat to study results. When data are collected in the context of a busy clinical environment, data collection points may be missed.

Despite these limitations, strengths exist. The randomized study design reduced bias and the use of a control comparator group adds to the strength of the conclusions. Use of a patient population in the context of clinical care facilitates immediate translation of the results and increases generalizability. Lastly, use of the recommended NIH task force criteria for chronic LBP and other baseline measures will aide in interpretation of the findings and advance research in this patient population.

Conclusions

Even though we did not observe a statistically significant difference between the three randomized groups in pain and anxiety pre/post injection change scores, we gained information that can be applied to future research projects. VR exposure in this patient population should be more robust and occur over a longer period of time with the use of additional tools measuring meaningful patient outcomes such as function, quality of life, and/or pain interference. Modification of study procedures and equipment to allow for delivery of the intervention during the injection procedure should be considered. In addition, population-specific content (i.e., the addition of guided imagery audio) and more comfortable positioning during content delivery may optimize intervention effectiveness. Lastly, this intervention was delivered effectively within the confines of a busy clinical practice with minimal interruption in patient care and no appreciable side-effects or complications. Virtual reality content may be a useful tool in rehabilitative pain management treatment programs and other practices caring for patients with chronic LBP and other chronic pain conditions.

Disclosure of conflict of interest

None.

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