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Virtual Reality in the Treatment of Fibromyalgia: A Pilot Study

Cristina Botella, PhD,[1,2] Azucena Garcia-Palacios, PhD,[1,2] Yolanda Vizcaíno, BA,[1] Rocio Herrero, BA,[1] Rosa Maria Baños, PhD,[2,3] and Miguel Angel Belmonte, MD[4]

Abstract

The aim of this article is to present preliminary data on the effectiveness of virtual reality (VR) as an adjunct to cognitive behavioral therapy (CBT) in the treatment of fibromyalgia (FM). The sample comprised six women diagnosed with FM according to the American College of Rheumatology guidelines (1990). The treatment program consisted of 10 sessions of group CBT with the support of an adaptive virtual environment containing a specific content for developing relaxation and mindfulness skills. Patients were assessed at pretreatment, posttreatment, and at a 6-month follow-up for the following outcome variables: functional status related to pain, depression, a negative and positive affect, and coping skills. The results showed the long-term benefits of significantly reduced pain and depression and an increased positive affect and use of healthy coping strategies. This is the first study showing a preliminary utility of VR in treating FM.

Introduction

PAIN IS THE MOST COMMON CAUSE of suffering and disability, affecting millions of people around the world. Fibromyalgia (FM) is a chronic musculoskeletal pain condition with unknown etiology, characterized by widespread pain accompanied by fatigue and disturbed sleep and mood (i.e., Ref.[1]). Patients remain symptomatic and do not improve over long periods of time once the disease is established. In addition, functional disability slowly worsens. Comorbidities with affective and anxiety disorders are common (i.e., Ref.[2]) and it is associated with frequent medical consultation and work disability, resulting in high economic and social costs. (i.e., Ref.[3]).

The prevalence of FM is estimated to be 2–7 percent in the general population[1,4] whose ages range from 40 to 60 years old. Cases have been reported at all ages, from children to the elderly.[5]

The scientific literature supports the conceptualization of this condition in an integrative biopsychosocial model that includes physiological, psychological, and social aspects (i.e., Ref.[6]). This integrative approach was possible thanks to important theoretical perspectives, such as the Gate Control Theory by Melzack and Wall,[7] who explained pain as operating through both biological and psychological mechanisms. The biopsychosocial model claims that pain is a complex condition involving biological, psychological, and social factors that have a negative impact on patients' quality of life. The treatment of FM has a poor prognosis for recovery (i.e., Ref.[8]) and it is considered a challenge for health professionals. Addressing FM from a multidimensional perspective seems to be more effective than from single approaches.[9,10]

The multidimensional perspective includes psychological programs as a promising treatment for FM. Psychological aspects such as self-efficacy, attention, appraisal of pain, or avoidance are among the best predictors of disability caused by chronic pain (i.e., Ref.[11]). There are several studies testing the efficacy of psychological programs for FM. In a recent and excellent meta-analysis study[12] that overcame some limitations hindering other review studies on this topic, 23 studies were reviewed that included 30 conditions and 1,396 patients. The psychological interventions were classified into six categories: cognitive-behavioral therapies (CBT), relaxation, educational interventions, behavioral treatments, mindfulness-based programs, and other treatments. The outcome variables analyzed included: average pain intensity, physical functioning, depression, sleep disturbances, and catastrophizing. The results revealed that the effect sizes of short- and long-term efficacies for psychological treatments were small yet robust. CBT was associated with the greatest effect sizes. Moderator analysis indicated that higher treatment doses lead to greater effect sizes. The authors concluded that

[1]Department Psicologia Basica, Clinica y Psicobiologia. Universitat Jaume I, Castellon, Spain.
[2]Ciber Fisiopatologia Obesidad y Nutricion, CB06/03 Instituto Salud Carlos III, Spain.
[3]Departament Personalidad, Evaluacion y Tratamientos Psicologicos, Universidad de Valencia, Valencia, Spain.
[4]Servicio de Reumatologia, Hospital General de Castellon, Castellon, Spain.

psychological programs are promising interventions for FM. However, they noted that there are relatively few studies on psychological treatment for FM, and they recommended carrying out more efficacy studies as well as studies exploring FM subtypes and mechanisms of action of psychological treatments. Another finding of these and other reviews is that although the results are promising, there is still room for improvement given that effect sizes are only small or moderate. Despite the programs' effectiveness, it is still limited and further research is needed to respond more appropriately to patients with FM. Information and Communication Technologies (ICT) can help to enhance the effectiveness of some components of treatment.

The use of ICT in the field of psychology has increased in the last few years. Virtual reality (VR), in particular, is used for treating several psychological disorders (e.g., Ref.[13]). In addition, VR is a powerful distracter: it provides a high degree of immersion to the user and can direct the individual's attention away from the real world and into the virtual environment. VR has been used in the treatment of acute pain associated with medical procedures. A seminal work was conducted by Dr. Hoffman's team at the University of Washington in studies that demonstrated the efficacy of VR as a distraction tactic in managing acute pain associated with medical procedures (e.g., wound care and physical therapy) for burn patients.[14,15] A recent systematic review about the use of VR distraction for pain reduction found promising results of the efficacy of this procedure.[16] The authors concluded that "the average person receiving some form of VR distraction for pain showed more improvement than about 83 percent of control subjects" (p. 1016).

In the field of pain, as previously mentioned, VR has been used mainly as a distraction strategy in treating acute pain associated with medical procedures. However, there is no such literature on applications of VR in the field of chronic pain. Ramachandran and Seckel[17] after carrying out an experiment with a mirror visual feedback on a FM patient suggested that mirrors and VR could be potential new treatments for this condition. Malloy and Milling[16] included a study by Leibovici et al.[18] reporting no difference in self-reported itching between VR distraction and non-VR distraction treatments in patients experiencing chronic pruritus; however, there appeared to be a difference in observer ratings of scratching. Malloy and Milling[16] stated that the results of this study were inconclusive. They also highlighted the differences between acute pain and chronic pain: VR distraction is a more appropriate procedure for specific moments such as when a patient is undergoing a painful medical procedure (experiencing acute pain). Chronic pain, on the other hand, is a complex condition wherein the patient is experiencing constant pain; distraction does not appear to be an effective technique for such a multidimensional condition. In fact, the recommendations for the treatment of chronic pain (see Ref.[19]) include combining pharmacological, physical, and psychological interventions. Among the psychological interventions, multicomponent programs appear to be more useful.

Our research team has initiated a line of research that explores the utility of ICT in psychological interventions for chronic pain. In this work, we present a study that preliminarily gauges the utility of VR as an adjunct for the application of two psychological techniques for treating FM: relaxation and mindfulness. To do this, we designed a CBT program supported by ICT for the treatment of FM. The VR system is an adaptive display that can include narratives, sounds, and visual cues to focus patients' attention on a component promoting positive emotions (e.g., relaxation) and to train patients to pay attention to stimuli not related to pain (e.g., through decentering and mindfulness skills). These components constitute an adjunct to a broader CBT program that includes education, cognitive therapy, active pacing, social skills training, and relapse prevention. The contribution of this article to the field of cybertherapy is to explore if VR can be useful and well-accepted by patients as an adjunct in the treatment of a complex condition as fibromyalgia.

Methods

Participants

Participants were recruited from the Rheumatology Service of a public hospital (Hospital General de Castellón). Some inclusion criteria were established; participants were required to: (a) have a diagnosis of FM by a rheumatologist and in accordance with American College of Rheumatology (ACR) criteria (1990); (b) be 18–65 years old; (c) not be suffering from severe mental disorders such as schizophrenia, bipolar, mental retardation, substance abuse or dependence, nor a mental disorder in need of immediate treatment (i.e., severe major depressive disorder); (d) not be suffering from a physical disease that could interfere with receiving a psychological treatment; and (e) not be in the process of requesting or suing for disability.

The sample comprised six women with a diagnosis of FM. The mean age of the sample was 55 years old (range = 47–65, $SD = 7.6$) and the mean duration of the FM diagnosis was 11 years. All participants agreed to participate in the study and signed an informed consent form. This research belongs to a funded project approved by an ethics review board.

All of the participants were married. Regarding occupation, 57.1 percent were homemakers and 42.9 percent were employed outside the home. As for education levels, 57.1 percent had completed elementary school, 28.6 percent had completed high school, and 14.3 percent had incomplete university studies. In addition to FM, 33.3 percent of the sample had a comorbid diagnosis of mood disorder, and took medication prescribed by a psychiatrist (antidepressants, SSRI). However, at the time of entering the study, the participants' mood disorders were in remission (they did not meet the Diagnostic and Statistical Manual of Mental Disorders 4th edition text revision [DSM-IV-TR] criteria for any mood disorders) as established by a structured diagnostic interview (structured clinical interview for DSM-IV disorders [SCID-1], First et al.[20]). Although 83.3 percent of the sample had a history of mood disorders, only one patient had previously received psychological treatment. Three patients were receiving stable doses of pregabalin for chronic pain. The other three patients were taking stable doses of pain killers, such as paracetamol or nonsteroidal anti-inflammatory drugs. Patients were told not to change the types of medication they were taking or to increase dosages while participating in the study unless instructed by a rheumatologist. None of them made medication alterations for the duration of the study.

Measures

The assessment protocol included the following measures related to pain and mood:

FM Impact Questionnaire (FIQ) (Burckhardt et al.[21]; Spanish version validated by Monterde et al.[22]): This instrument assesses physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, morning tiredness, and well-being in patients with FM. This is a self-report questionnaire originally developed and validated in English for use with patients with FM. The FIQ is composed of ten questions, with each question rated on a four-point Likert-type scale. The first question contains 11 items related to the ability to perform large muscle tasks. Items 2 and 3 ask the patients to mark the number of days they felt well and the number of days they were unable to perform work (including housework) because of FM symptoms. Items 4 through 10 are horizontal linear scales of 10 increments on which the patients rate work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression.

Chronic Pain Coping Inventory[23,24]: This instrument identifies coping strategies that patients use to deal with chronic pain. It is a 64-item measure that was designed to assess coping subscales that fall into three categories: illness-focused coping (Guarding, Resting, and Asking for Assistance), wellness-focused coping (Relaxation, Task Persistence, Exercise/Stretch, and Coping Self-Statements), and neutral coping (Seeking Social Support subscale). Each item is scored on a frequency scale ranging from 0 to 7, corresponding to the number of days that the individual used each of the strategies during the previous week. Subscales demonstrate adequate to good internal consistency ($\alpha = 0.74$) and validity. There is no Spanish validation of this scale; hence, we translated the instrument. In a sample of 50 women suffering from FM with a mean age of 48 years, attending our center, we obtained the following data: Guarding ($M = 2.79$, $SD = 1.45$); Resting ($M = 3.52$, $SD = 1.52$); Asking for Assistance ($M = 2.48$, $SD = 1.39$); Relaxation ($M = 2.21$, $SD = 1.24$); Task Persistence ($M = 4.39$, $SD = 1.95$); Exercising ($M = 2.86$, $SD = 1.44$); Coping Self-Statements ($M = 2.56$, $SD = 1.66$); Seeking Social Support ($M = 1.97$, $SD = 1.28$). These data are similar to those obtained in other validation studies of the chronic pain coping inventory (CPCI) (e.g., Ref.[25]).

Beck Depression Inventory II (BDI-II, Beck et al.,[26] Spanish validation by Sanz et al.[27]): This is one of the most used self-report instruments to assess depression. It presents good psychometric properties. This inventory includes 21 items evaluating cognitive, behavioral, affective, and somatic symptoms of depression. A score from 0 to 13 indicates minimal depression, from 14 to 19 mild depression, from 20 to 28 moderate depression, and from 29 to 63 severe depression.

Positive and Negative Affect Schedule (PANAS, Watson et al.[28] Spanish validation by Sandín et al.[29]): This is a 20-item self-report instrument assessing the occurrence of the negative and positive affect. Each item is rated in a 1 to 5 intensity scale. The scale offers a total score for the positive affect and negative affect with scores ranging from 10 to 50. This instrument offers good internal consistency and convergent and discriminate validity.

Patients were evaluated using all of the above measures for three assessment periods: pretreatment, post-treatment, and a 6-month follow-up.

VR Satisfaction Scale: This scale, adapted from one of the items of the scale designed by Borkovec and Nau,[30] was used to measure satisfaction with the VR component only after completion of the treatment. Participants were asked, "How satisfied are you with the use of VR in the psychological program you received?" The participants rated satisfaction on a 0 to 10 scale, where 0 was "not satisfied at all" and 10 was "completely satisfied." Participants also rated two more specific questions on a scale from 0 to 10 (where 0 was "not at all" and 10 "very much"): "To what extent were VR sessions useful in practicing the therapeutic techniques at home?" and "To what extent were VR sessions useful in getting more involved in the treatment?"

Treatment

The treatment was a group CBT program for FM supported by VR for the delivery of relaxation and mindfulness. The treatment was designed according to the guidelines of the existing CBT programs.[31] The program included ten 2-hour group sessions. Sessions 1 through 6 were delivered twice a week for 3 weeks, whereas sessions 7 through 10 were delivered weekly for 4 weeks. Session frequencies were designed to provide a more intensive intervention during the first six sessions in which the participants could learn and practice the therapeutic strategies with the therapists; later sessions were less frequent to promote patients' generalization and practice of the strategies with less support from the therapists. Two therapists participated in the treatment sessions. The treatment program included the following components:

1. Education about chronic pain and FM: Participants were given descriptions of the biopsychological model of chronic pain and FM, the psychological, biological, and social factors influencing the experience of pain and other FM symptoms, and the rationale of the CBT program for the treatment of FM.
2. Relaxation. Participants were given the rationale for using relaxation to reduce high levels of the negative affect, hyperarousal, and sleep difficulties and were provided with VR-supported training in slow breathing. While presenting the VR scenario, the system provided instructions for slow breathing for 10 minutes; next, the system instructed the patients to continue breathing slowly for 10 more minutes, while enjoying a peaceful view and the sounds of a beach or a meadow. Participants were instructed to practice the breathing training at home (for 15–20 minutes per day) with a CD and to evoke the images and sounds of the VR environment.
3. Activity pacing and behavioral therapy: Participants were provided with the rationale for activity pacing (balancing an activity with periods of rest by means of meaningful programmed activities to achieve a healthy level of activity, promoting self-efficacy, and decreasing the negative affect and avoidance of activities because of pain. Education was provided about healthy habits to manage symptoms related to sleep, eating, and sexual activity. As a side benefit, this component also helps to structure life areas (family, relationship, work, and leisure) in a more healthy and satisfying way.
4. Cognitive restructuring: The rationale for cognitive therapy was provided (e.g., the strong role catastrophizing plays in maintaining chronic pain and the possibilities for change in thoughts for better management of FM), along with practice in cognitive restructuring.

Table 1. Content of Cognitive Behavioral Therapy Program Supported by Virtual Reality

Session 1: Education about chronic pain and FM.
Session 2: Introduction to mindfulness and introduction to activity pacing.
Session 3: Education about healthy habits and introduction to relaxation.
Session 4: Introduction to cognitive restructuring. Practice of activity pacing, relaxation, and mindfulness (VR).
Session 5: Practice of activity pacing, cognitive restructuring. Practice of mindfulness and relaxation (VR).
Session 6: Practice of activity pacing, cognitive restructuring. Practice of mindfulness and relaxation (VR).
Session 7: Introduction to effective social skills. Practice of activity pacing, cognitive restructuring. Practice of mindfulness and relaxation (VR).
Session 8: Practice of activity pacing, cognitive restructuring, and social skills. Practice of mindfulness and relaxation (VR).
Session 9: Practice of activity pacing, cognitive restructuring, and social skills. Practice of mindfulness and relaxation (VR).
Session 10: Relapse prevention.

FM, fibromyalgia; VR, virtual reality.

5. Mindfulness: Participants were instructed in the rationale for mindfulness as a treatment for FM (e.g., its role in focusing attention on pain and other pain-maintenance symptoms, paired with the possibility of refocusing attention on the present moment and on other cues unrelated to pain). Participants were also taught mindfulness skills[32] to observe, describe, and participate in experiences in the present moment without judging and while decentering from pain. While participants were immersed in the VR, the system provided instructions on how to observe the different elements offered by the beach and the meadow scenarios (e.g., the view and sounds of the sea, the waves, seagulls, and the sun rising over the horizon), how to remain focused in the present moment, and how to participate in the experience without making any judgments. As for the experience of pain, they were asked to observe it, and then direct their attention to other visual and audio stimuli offered by the VR scenarios. As a homework assignment, patients were asked to practice the same skills in the real world using the stimuli offered by the various activities and experiences. The goal of this component is to accept pain as one experience, but also to realize that other concurrent stimuli are present at all times.
6. Relapse prevention: Participants were offered an overview of the program to help resolve their doubts and to answer their questions about the different strategies they learned. They were also assisted in planning how to use the strategies in the future and were instructed on how to anticipate and confront high-risk situations.

The session format was as follows: (a) Overview of the last session and the introduction of an agenda; (b) Homework review; (c) Specific content of session; and finally, (d) Homework assignment. In Table 1 we offer the content of the treatment program.

Therapists

Two therapists participated in the study: a main therapist and a co-therapist. The role of the therapist was to apply the treatment. The role of the co-therapist was to procure and prepare all the materials needed for each session, including the VR equipment, and to support the therapist in applying the treatment. The therapist and co-therapist held Ph.D. degrees and were experts in the delivery of CBT, with 12 and 7 years of clinical experience, respectively.

Virtual environments description

The following devices were used in this study: two personal computers (PCs), a large projection screen, two projectors, a wireless pad, and a speaker system. PC#1 had the graphical outputs from its graphic card connected to two projectors (with a resolution of 1,024×768 pixels and a power of 2,000 lumens). They were used to project the environment onto a horizontal screen of 4×1.5 meters that was placed on one of the walls of the room. The patients were seated on the other side of the room to best view the VR scenarios. A wireless pad was placed on a table on the other side of the room, close to PC#2. The therapist sat next to this PC, from which the application and the features of the virtual environment shown to the patient could be controlled. In this study, the therapist used the pad to instruct the patients to move around the environment, while receiving therapeutic instructions (see Fig. 1).

The application used in this research is called Engaging Media for Mental Health Applications (EMMA's) World and

FIG. 1. Treatment setting for the delivery of virtual reality (VR) sessions for training in relaxation and mindfulness skills in a group format. Color images available online at www.liebertpub.com/cyber

was developed within the framework of a research project funded by EU (IST-2001-39192-EMMA). EMMA's World includes five scenarios designed to provoke different emotional reactions: a desert, a beach, a forest, a snowy landscape, and a meadow. The main advantage of this VR environment is flexibility. The therapist can include different elements (music, sounds, narratives, varying weather, colors, texts, etc.) in the five scenarios to apply therapy using different emotions and different problems. This system has been validated as a mood induction procedure[33,34] and it has proven useful for activation and processing of emotions in post-traumatic stress disorder,[35] pathological grief,[36] and adjustment disorders.[37]

In this study, we used two of the five scenarios: the beach and the meadow. In the beach scenario, the users can see the sea, waves, palm trees, seagulls, and a small sailboat on the horizon. They can hear birdcalls, waves, and footsteps in the sand. In the meadow, the users can see green grass, flowers, leafy trees, rocks, and butterflies in motion. They can hear birdcalls, footsteps in the grass, and different kinds of music.

For this study, audio instructions for slow breathing were also included. The patients, in a group format, observed the beach or the meadow, while receiving instructions about slow breathing and listening to the sounds of the beach or the meadow. The patients were given mindfulness instructions (i.e., to observe, describe, and participate in experiencing the present moment) to focus their attention on the audio and visual cues offered by the scenarios to promote decentering from pain (see Fig. 1). To promote immersion, a large screen and a surround audio system was used. One of the therapists controlled the interaction with the VR environment by means of a pad. When entering the VR environment, there were instructions of focusing the attention in the VR environment, and the participants could tell the therapist to action the pad to walk around making the walking a group experience directed by the participants taking turns. The participants also had the chance to operate the pad, but they preferred the therapist to do it.

Procedure

The present study was conducted at the Universitat Jaume I in Castellon, Spain. One of the rheumatologists from the larger public hospital in the area (Author M.A.B.) referred FM patients in need of psychological treatment to the study. Participants visited the university clinical psychology center and were evaluated for the inclusion criteria. Participants were offered the psychological treatment and were asked to sign an informed consent form. The participants filled out the pretreatment assessment protocol in one assessment session with the help of a clinician. Next, they received the treatment program that included ten 2-hour sessions delivered in 7 weeks. After the completion of the treatment, they were assessed with the post-treatment protocol. After 6 months, they were assessed again (a 6-month follow-up).

Results

Table 2 shows the scores of each patient in the different measures at the pretest, post-test, and follow-up.

Table 3 shows the means and standard deviations of the participants' scores in the variables chosen for this investigation at the three assessment periods: pretreatment, post-treatment, and the 6-month follow-up. Cohen's d was performed to report the effect size of the differences between the scores from pretreatment to post-treatment and from pretreatment to the 6-month follow-up.

The scores for the FIQ, measuring levels of functional status of the FM patients, showed a slight reduction from the

Table 2. Scores of Each Participant in the Selected Outcome Variables at Pretreatment, Post-Treatment, and 6-Month Follow-Up

	Pretreatment						*Post-treatment*						*6-month follow-up*					
	P1	P2	P3	P4	P5	P6	P1	P2	P3	P4	P5	P6	P1	P2	P3	P4	P5	P6
BDI	33	6	11	17	23	11	14	3	12	12	8	6	18	3	13	17	9	8
PANAS																		
Positive	25	34	24	16	17	17	27	41	33	18	40	20	28	37	28	20	41	33
Negative	36	14	22	24	21	13	23	10	29	24	23	14	24	13	28	23	22	14
FIQ	78.4	48	66.3	55.2	53.7	46.7	73.4	46	62	54.9	46.2	35.6	58.2	42.5	60.4	50.5	36.3	33.5
CPCI																		
Guarding	1.89	5.44	2.67	1.67	1	2.33	1.56	3.11	2.56	1.89	2.11	3.11	1.89	4.20	4.11	2	3.11	4.20
Resting	0.57	7	4.29	3.14	0.14	3.71	1.43	5	2.57	3.71	1.86	5.43	1	6	3.14	4	2.11	4.89
Asking for assistance	2.75	3.50	2.50	2.25	1.75	2	1.75	2.75	2.75	2	3.50	2.25	1.75	2.50	3	1.50	4	3.11
Structured relaxation	2.14	6	2.86	1.43	2.29	2.57	2.86	5.43	3	1.86	3.29	5.57	2	5.43	3.57	1.57	3.11	4.71
Task persistence	6.67	4.67	3.33	2.33	2.50	3.67	6.83	4.33	3.17	1.83	3	4.50	6.80	4.67	1.67	2.50	3.11	3.25
Exercising	5.75	5.25	3.58	2.25	1.17	2.17	4.17	6.17	3.42	2.33	5.42	4.17	2.80	6.75	3.17	2	5.50	4.86
Coping self statements	4	1.36	2.27	0.82	1	2.45	5.09	1	4.09	0.27	4.36	4.64	2.55	5.73	3.55	0.81	4.11	4.50
Seeking social support	1.50	1.75	1.75	4.25	0.25	1.25	1	1.63	2.63	4.50	4.25	3.75	3	4	3.13	3.37	4.17	3.50

P1: Participant 1; P2: Participant 2; P3: Participant 3; P4: Participant 4; P5: Participants 5; P6: Participant 6.

BDI, beck depression inventory; PANAS, positive and negative affect schedule; FIQ, fibromyalgia impact questionnaire; CPCI, chronic pain coping inventory.

Table 3. Means, Standard Deviations and Cohen's d at the Three Assessment Periods

	Pretreatment		*Post-treatment*		*6-month follow-up*		*Cohen's d*	
	M	*SD*	*M*	*SD*	*M*	*SD*	*Prepost*	*Pre-follow-up*
BDI	16.83	9.84	9.16	4.21	11.33	5.75	1.01	0.68
PANAS								
Positive	22.17	6.97	29.83	9.83	31.17	7.47	−0.84	−0.99
Negative	21.67	8.31	20.5	7.06	20.67	5.92	0.15	−0.14
FIQ	58.05	12.15	53.01	13.40	46.90	11.26	0.39	0.95
CPCI								
Guarding	2.5	1.54	2.39	0.64	2.25	1.09	0.093	0.19
Resting	3.14	2.53	3.33	1.65	3.52	1.83	−0.09	−0.17
Asking for assistance	2.45	0.62	2.5	0.63	2.64	0.92	−0.08	−0.24
Structured relaxation	2.88	1.6	3.66	1.49	3.39	1.5	−0.50	−0.33
Task persistence	3.86	1.61	3.94	1.71	3.66	1.82	−0.05	0.12
Exercising	3.36	1.83	4.28	1.37	4.18	1.81	−0.57	0.45
Coping self statements	1.98	1.18	3.24	2.05	3.54	1.70	−0.75	−1.07
Seeking social support	1.79	1.32	2.96	1.44	3.53	0.47	−0.85	−1.76

Cohen's effect size estimate (d > 0.80 = large, d > 0.50 = moderate, d > 0.20 = small).

pretest to post-test. The most important result is that participants continued to improve in the follow-up period, achieving a higher reduction in the impairment caused by FM from the pretest to follow-up. Changes in this variable were more prominent in participants 1, 5, and 6.

The scores for the BDI indicated that levels of depression were not clinically significant at the pretest. Nevertheless, there was a reduction from the pretest to post-test. The BDI scores at the follow-up continued to indicate low levels of depression. The decrease was more prominent in participants who scored above the scale's cutoff score (19): participants 1 and 5. None of the participants scored above 19 at the follow-up.

Results indicated an increase in the positive affect at the post-test that continued to increase from the post-test to follow-up. The negative affect measured by this scale did not achieve changes from the pretest to post-test and follow-up. Only participant 1 (who had had a higher score in this measure) achieved an important decrease in the negative affect. This participant had also had a higher score in depression as measured by the BDI.

Results regarding the use of coping strategies showed no changes in the use of illness-focused coping from the pretest to post-test and follow-up (Guarding, Resting, and Asking For Assistance); there was an increase in Seeking Social Support (neutral coping) that continued to increase at the follow-up. Regarding the use of wellness-focused coping, we found a high increase in coping self-statements from the pretest to post-test that continued at the follow-up, a moderate increase in the use of Relaxation and Exercise/Stretch, and no changes in Task Persistence. The scores for each participant (Table 2) demonstrate the variability in the scores.

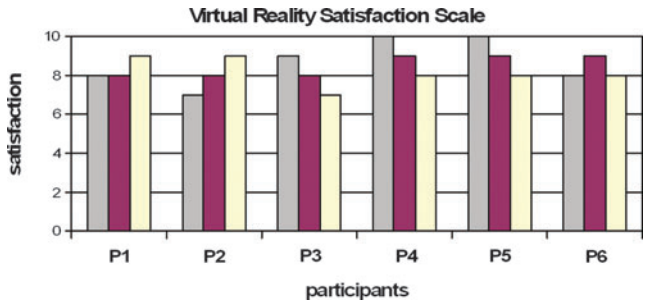

FIG. 2. Participants' ratings for (a) overall satisfaction with VR (first bar); (b) To what extent were VR sessions useful for practicing the therapeutic techniques at home? (second bar); and (c) To what extent were VR sessions useful for becoming more involved in the treatment? (third bar). Color images available online at www.liebertpub.com/cyber

Participants rated their levels of satisfaction with the use of VR in the CBT program on a scale from 0 to 10. Participants also rated two more specific questions from 0 to 10 (where 0 was "not at all" and 10 "very much"): "To what extent were VR sessions useful when practicing the therapeutic techniques at home?" and "To what extent were VR sessions useful in becoming more involved in the treatment?" Each patient's ratings are shown in Figure 2. The levels of satisfaction ranged from 7 to 10.

Discussion

This is the first study exploring the possibility of VR use as an adjunct to CBT in the psychological treatment of FM. The results indicated that VR was well-accepted by six patients, who reported high levels of satisfaction with its use. Furthermore, the CBT program, which included VR as an adjunct to deliver relaxation and mindfulness improved in key variables related to FM. Functional status measured by the FIQ improved mainly during the 6 months following the end of the treatment. The scores showed a reduction in the impairment caused by FM symptoms. Depression also decreased, although a scale measuring the negative affect did not show significant reductions. Notably, at no point was the level of depression in this sample clinically significant (the cutoff score in the BDI for significant symptoms is 19), nor was the level of the negative affect (normative data of the general negative affect in women from the general population in the Spanish validation conducted by Sandín et al.[29] is a mean of 20.61, *SD* = 6.54); (see Table 2). The participant who scored higher in the BDI and in the PANAS-Negative affect (participant 1) achieved an important reduction in both measures, indicating an improvement in the negative affect. Regarding the positive affect, our sample showed low levels of the positive affect at

the pretest that increased progressively until the follow-up assessment (normative data of the general positive affect in women from the general population in the Spanish validation conducted by Sandín et al.[29] is a mean of 30.23, $SD = 6.16$); (see Table 2). Therefore, the treatment achieved an important improvement in functional status and the positive affect.

The main objective of CBT is to increase the use of strategies to cope with pain and other symptoms. As previously mentioned, we measured coping with the CPCI. The findings indicated a high increase in the use of coping self-statements and a moderate increase in the use of relaxation and exercising, both healthy coping strategies. There were no changes in another healthy coping skill, task persistence. On the other hand, there was an increase in seeking social support, a neutral coping skill. As for the unhealthy coping strategies (guarding, resting, and asking for assistance), there were no changes. The CBT program included components related to learning the healthy coping skills included in the CPCI (cognitive restructuring, activity pacing, mindfulness, and relaxation) as well as the neutral coping skill Seeking for Assistance (social skills). The detailed scores in Table 2 show that at the pretest, the levels of use of some skills (Seeking for Assistance and coping self-statements) were very low; however, they largely increased due to treatment. As for the other healthy skills, including relaxation and exercising, the pretest scores were already high, perhaps, because the patients had already been informed by their rheumatologists and other medical staff about the roles exercise and relaxation plays in managing FM. The level of task persistence was also high at the pretest, an effect, perhaps, demonstrated by participants' willingness to visit our clinical center twice a week to receive an intensive psychological treatment. The pretest score in task persistence might reflect a high level of motivation and willingness to confront their medical condition. It would be interesting to determine in future studies if this variable is a moderator of important issues, such as treatment adherence and attrition. In our case, retention rates for both treatment and the 6-month follow-up assessment were 100 percent.

We had predicted a reduction in the unhealthy coping skills; however, there were no significant changes in these variables. The patients had been suffering chronic pain for many years (the average duration since FM diagnosis was 11 years, and they had been suffering symptoms for some time before they were officially diagnosed). In those years, they were, perhaps, using unhealthy coping skills. Therefore, at the moment of entering the treatment, we could presume that those skills were very well established in the patients' behavior repertoire. It is important to study the effort and time needed to effect a change in embedded, unhealthy behaviors in chronic conditions like FM. Some findings already support the idea of a positive relationship between a greater efficacy and the length of treatment.[12] The time, effort needed, and content of the psychological programs are important issues to study to improve treatment programs for FM.

Another notable finding is the important increase in the positive affect. Our research team is striving to understand the role positive emotions play in CBT's success, in the context of the positive psychology paradigm.[38] In the field of chronic pain, our goal is to promote positive emotions to enhance the effect of activity pacing. Our goals are consistent with the new transdiagnostic CBT approaches that emphasize the use of emotion-focused strategies.[39]

Another aspect worth highlighting is the patients' acceptance of the use of VR. The level of overall satisfaction with the VR system was very high. Participants agreed that the use of VR helped them to become involved in the treatment, and they considered VR useful in practicing the therapeutic techniques at home. The patients reported recalling the images of the VR scenarios to practice relaxation and mindfulness at home, which made it easier to remember to do the practice. The profile of a typical FM patient in Spain is a middle-aged woman with an elementary level of education who has little experience or familiarity with ICTs. One of our concerns was that patients could reject ICTs or feel uneasy using them for treatment. This initial pilot study encourages us to continue exploring the use of ICT-based applications with this population. Our research team is exploring the use of VR in the delivery of other therapeutic components, such as behavior activation. Furthermore, we are studying the use of mobile devices (including personal digital assistants and cell phones) for the Ecological Momentary Assessment and for the delivery of therapeutic programs at home. The attractiveness of VR for this population could be an advantage of VR-CBT programs over traditional CBT that could encourage FM patients to enroll in psychological treatments, an issue in the chronic pain population, who do not always accept a psychological program because they consider their problem only treatable from a medical approach. Another issue regarding VR is the economic cost. In our program, VR is applied in a regular group therapy room and the devices to deliver VR are usually part of the equipment that any clinic or hospital has (regular computer, projector, and large screen). Our research team has always been aware of the importance of cost in the dissemination of VR and our VR environments have been designed to be applied with affordable cost for the final user (in this case, rheumatology clinics, rheumatology departments in hospitals, or mental health units providing health psychology services).

This study has its limitations. It is a pilot study aimed at exploring whether VR could be used in a CBT program for FM. Given the complexity of this disorder, we began by using VR not as a sole technique, but as an adjunct to a broader CBT program; this allowed us to support the training of two psychological strategies: mindfulness and relaxation.

Conclusions

A multicomponent cognitive-behavioral program using VR as a tool to deliver relaxation and mindfulness produced long-term benefits in a small subset of FM patients. VR was well-accepted by the patients, who achieved important improvements in key variables like functional status, affect, and coping skills. Of course, we cannot necessarily conclude that VR was the key element in achieving these results, since it was just one component of the treatment program. However, it was proven that it is possible to use VR in a small sample suffering from a chronic condition, that the use of this technology did not interfere with the delivery of the treatment, and also, that it was well-accepted by the patients. The main contribution of this work is in its ground-breaking status as the first study to explore the efficacy of VR as an adjunct to CBT in FM. These findings encourage us to continue with this line of research, to explore the use of VR in the delivery of other components like activity pacing and behavior activation, and to conduct more rigorous controlled studies.

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Address correspondence to:
Prof. Azucena Garcia-Palacios
Department Psicologia Basica
Clinica y Psicobiologia
Universitat Jaume I
Avda Vicent Sos Baynat s/n
12071 Castellon
Spain

E-mail: azucena@psb.uji.es