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5 The use of VR in the treatment of panic disorders and agoraphobia

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Abstract Panic disorder with agoraphobia (PDA) is considered an important public health problem [1-3]. The efficacy of cognitive-behavioral therapy (CBT) for PDA has been widely demonstrated [4, 5]. The American National Institute of Health [6] recommended Cognitive-Behavioral programs as the treatment of choice for this disorder. This institution also recommended that researchers develop treatments whose mode of delivery increases the availability of these programs. Virtual Reality based treatments can help to achieve this goal. VR has several advantages compared with conventional techniques. One of the essential components to treat these disorders is exposure. In VR the therapist can control the feared situations at will and with a high degree of safety for the patient, as it is easier to grade the feared situations. Another advantage is that VR is more confidential because treatment takes place in the therapist's office. It is also less time consuming as it takes place in the therapist's office. Considering the wide number of situations and activities that agoraphobic patients use to avoid, VR can save time and money significantly. Another advantage in treating PDA using VR is the possibility of doing VR interoceptive. VR could be a more natural setting for interoceptive exposure than the consultation room because we can elicit bodily sensations while the patient is immerse in VR agoraphobic situations. Finally, we think that VR exposure can be a useful intermediate step for those patients who refuse in vivo exposure because the idea of facing the real agoraphobic situations is too aversive for them.
In this chapter we offer the work done by our research team at the VEPSY-UPDATED project. We describe the VR program we have developed for the treatment of PDA and we summarize the efficacy and effectiveness data of a study where we compare a cognitive-behavioral program including VR for the exposure component with a standard cognitive-behavioral program including in vivo exposure and with a waiting list control condition. Our findings support the efficacy and effectiveness of VR for the treatment of PDA.

1. Introduction

The essential feature of Panic Disorder is the experience of unexpected and recurrent panic attacks. A panic attack is a discrete and sudden episode of intense fear with several anxiety

symptoms (dyspnea, dizziness, palpitations, trembling, sweating, nausea, dizziness, fear of dying or losing control, etc). Many people who have panic attacks also avoid situations that they associate to panic (situations in which escape might be difficult or help not available, as being in a crowd, traveling in a bus or train, standing in line or staying at home alone).

This avoidance behavior is called Agoraphobia [7, 8].

Panic disorder with agoraphobia (PDA) is today considered to be an important public health problem [1-3]. The efficacy of cognitive-behavioral therapy (CBT) for panic disorder and agoraphobia has been widely demonstrated [4, 5]. The American National Institute of Health [6] recommended Cognitive-Behavioral programs as the treatment of choice for this disorder. This institution also recommended that researchers develop treatments whose mode of delivery increases the availability of these programs. From this perspective, it is also possible to understand the increasing insistence on considering two axes to test psychological programs: the efficacy Axis, or axis of internal validity, and the effectiveness, or clinical utility Axis [9].

With respect to Axis I, at the present time we have at our disposal treatment programs that are supported by well designed empirical studies. However, there is still a long way to go before these programs can be recommended as a standard alternative that could reach a high number of panic sufferers. That is, it is important to progress in the Axis II or clinical utility of CBT programs for PDA. Virtual Reality and telepsychology based treatments can help to achieve this goal. VR has several advantages compared with conventional techniques.

In this chapter we offer the work done by our research team at the VEPSY-UPDATED project. The aim of the following sections is, on one hand, to describe the clinical protocols and the prototypes of the Virtual Reality designed by our group at Jaume I University, Valencia University and Politechnic University of Valencia to assist the exposure component of a cognitive-behavioral program for treating panic disorder with agoraphobia (PDA). On the other hand, we have conducted a large-scale clinical trial to obtain data about the efficacy and effectiveness of VR exposure vs. In vivo exposure in the treatment of PDA. We summarize the efficacy and effectiveness data of that study where we compare a cognitive-behavioral program including VR for the exposure component with a standard cognitive-behavioral program including in vivo exposure and with a waiting list control condition. Our findings support the efficacy and effectiveness of VR for the treatment of PDA. We finish this chapter discussing our results and pointing at several future directions.

2. Treatment of panic disorder and agoraphobia

2.1 Traditional treatment of panic disorder and agoraphobia

As we have already mentioned, the effectiveness of cognitive-behavioral therapy for panic disorder and agoraphobia has been widely demonstrated [4, 5]. These interventions have shown higher effectiveness that waiting-list, supportive therapy, relaxation, and placebo control [10]. These programs offer the highest effectiveness and the lowest drop-out rates compared to pharmacotherapy and combined treatments [11]. The American National Institute of Health [6] recommended Cognitive-Behavioral programs as the treatment of choice for this disorder. This institution also recommended that researchers develop treatments whose mode of delivery increases the availability of these programs. From this perspective, it is also possible to understand the increasing insistence on considering the two aspects that are taken into consideration in the clinical guide (*Template for Developing*

Guidelines: Interventions for Mental Disorders and Psychosocial Aspects of Physical Disorders) that has been developed by the committee of experts of the *American Psychological Association* within the framework for "empirically valid treatments or treatments based on evidence" [9]. This guide recommends to take into account two "Axes": the efficacy Axis, or axis of internal validity, which entails analyzing the scientific evidence that is available for any given intervention, and the effectiveness, or clinical utility Axis, which entails analyzing the possibility of the intervention in the specific context in which it has to be offered [12, 13]. In the opinion of the group that developed the guide, all this indicates to what degree the intervention will be useful in the clinical situation in which it is going to be applied, i.e. it means taking into account among other factors: the generalizability of the administration of the the intervention in a variety of contexts; the feasibility of the intervention through patients and contexts, and the cost and benefits associated with the administration of the intervention [4].

With respect to Axis I of the clinical guide, at the present time we have at our disposal treatment programs for PD, with or without agoraphobia, supported by empirical studies of exceptional methodological rigor. The "well-established" treatments that have so far shown themselves to be the most effective up until now are the treatment for the control of panic developed by the Barlow group [14-16] and the cognitive therapy developed by the Clark group [17, 18]. In both cases, we are dealing with very clear and structured manualised treatments [4]. As far as the efforts that have been carried out so far in respect to Axis II, there is already evidence about the utility of the brief programs supported by self-help materials in the treatment of PD [19-21]. There is still a long way to go, however, before these programs can be recommended as a standard alternative that could substitute existing programs [4]. Other aspects of Axis II have begun to be studied, such as for example the feasibility of the treatment (e.g. ease of dissemination) or generalizability (degree to which its application is backed up in clinical practice). A study carried out by Wade, Treat & Stuart [22] demonstrated that cognitive-behavioral programs designed in controlled studies were transportable to a public mental health care population. These results were maintained in a one-year follow-up [23]. Our research team has obtained similar results in a recent study [24].

The treatment of PDA has improved dramatically in the last years. However, researchers have to continue studying ways of application of cognitive-behavioral programs that consider cost-benefit issues as availability, feasibility and ease of application. Virtual Reality based treatments for PDA can help to achieve this goal.

2.2. Virtual reality treatment for panic disorder and agoraphobia

Virtual Reality is a new technology that has great potential for Clinical and Health Psychology as it provides alternatives for assessment, treatment, training, and research, which are not available using conventional psychological methods.

Regarding PDA, VR has several advantages compared with conventional techniques to treat this disorder. One of the essential components to treat these disorders is exposure. Traditionally, exposure is carrying out in vivo or using imagery. In in-vivo exposure patients undergo graded exposure to what they fear most with the help of a psychologist. In comparison with this type of technique, in VR the therapist can control the feared situations at will and with a high degree of safety for the patient, as it is easier to grade the feared situations. Another advantage is that VR is more confidential because treatment takes place in the therapist's office, and patients need not fear to be exposed in public or simply that their problem might be known. Besides, it is much cheaper as it takes place in the therapist's office, and considering the wide number of situations and activities

that agoraphobic patients use to avoid, VR can save time and money significantly. In imaging exposure, psychologists train patients to cope with what they fear using imagination techniques, asking patients to imagine as exactly as possible that what they fear is happening. Compared to this technique VR is more immersive because it stimulates several sensory modalities (audio, visual, and vestibular). This can be of great help to people who have difficulties imagining scenes. The therapist also knows what the patient is seeing at all times and can therefore know more easily and accurately which stimulus is provoking the fear response.

Another advantage in treating PDA using VR is the possibility of doing VR interoceptive exposure at the same time of conducting situational exposure. Interoceptive exposure consists of exposing patients to bodily sensations similar to the ones experienced in their panic attacks. This can be achieved carrying out several tasks in the consultation room, such as blowing through a straw, hyperventilate, running, etc. We think that VR could be a more natural setting for interoceptive exposure than the consultation room because we can elicit bodily sensations while the patient is immerse in VR agoraphobic situations.

Finally, we think that VR exposure can be a useful intermediate step for those patients who refuse in vivo exposure because the idea of facing the real agoraphobic situations is too aversive for them. We think that making those patients go through a VR exposure treatment can increase the likelihood that they accept an in vivo exposure program afterwards.

All this advantages has guide our work regarding the design and testing of a VR exposure program for treating PDA.

There are already some studies about the use of VR and panic disorder/agoraphobia.

Jang, Ku, Shin, Choi & Kim [25] informed that most of the patients had difficulties to become immerse in the VR environment. Vincelli, Choi, Molinari, Wiederhold & Riva, [26] described a VR treatment protocol for PDA, but they did not offer efficacy data. Finally, Moore, Wiederhold, Wiederhold & Riva [27] presented VR environments that activated arousal in a subclinical sample but they did not offer efficacy data.

3. The clinical protocols

3.1. Assessment protocol

The assessment protocol was designed following the guidelines of the National Institutes of Health Consensus Development Conference on the Treatment of Panic Disorder held in October 1992 and reported in Shear and Maser [28]. The objective of this conference was to develop a standard assessment package for Panic Disorder (PD). The main topics in PD assessment are: a) Structured diagnostic assessment; b) Panic attacks and limited symptom episodes; c) Anticipatory anxiety; d) Phobic symptoms; e) Overall functioning, global severity and improvement; f) Comorbidity and coexisting symptoms.

Besides the topics recommended by these authors, we have included new topics that a recent review of the scientific literature about panic and agoraphobia has revealed. These new topics are related with the axis II or clinical utility axis of the clinical guide (*Template for Developing Guidelines: Interventions for Mental Disorders and Psychosocial Aspects of Physical Disorders*) that has been developed by the committee of experts of the *American Psychological Association* within the framework for "empirically valid treatments or treatments based on evidence" [9]. The more important topic that we have included is the satisfaction and acceptance of the treatment program.

In the next section we describe the assessment protocol we have designed.

3.1.1. Diagnostic instruments

The instruments used to establish the diagnosis are the following:

Screening Interview: This instrument, developed by our group, screens information about demographic variables, reasons for seeking treatment, duration of the disorder, perceived severity, past treatments, alcohol and substance intake, and presence of physical illness. The instrument also screens the occurrence of possible anxiety disorders.

Consent Form: Patients will read and sign an informed consent form about the study before starting the assessment phase.

Medication control: During the study, the patient cannot increase the medication dosage. However the patient can start taping medication when he/she feels better with the guide of a psychiatrist. This is an index of improvement that should be recorded using this instrument. The therapist has a record of the type and dosage of medication throughout all the process.

Diagnostic Interview (ADIS-IV-L) [29]: It is a semi-structured interview that assesses the DSM-IV anxiety disorders and mood disorders and screens for other major disorders. We will use the sections for PD and AG.

Agoraphobic Avoidance and Fear Scale: Adapted from Mark and Mathews [30]. The patient and the therapist establish 4 behaviors or situations that the patient avoids because of panic and agoraphobia. He rates the level of avoidance in a 0-10 scale where 0 = *I never avoid it* and 10 = *I always avoid it*; and the level of fear in another 0-10 scale, where 0 = *No fear* and 10 = *Extreme fear*.

Degree of Belief in Catastrophic Thoughts: The main catastrophic thoughts related to panic attacks in target behaviors or situations are specified. The degree of belief in those thoughts is assessed in a scale ranged from 0% to 100%: when 0% means that the patient does not believe the thought at all, and 100% means that the patient believes that the thought is totally true.

Inclusion and exclusionary criteria: To take part in the study, patients should meet DSM-IV diagnostic criteria for panic disorder (with or without agoraphobia) or for agoraphobia (with or without PD history). The exclusionary criteria are severe major depression or psychosis, current alcohol or drug dependence, and severe physical illness.

Panic attack record: Following Shear and Masser's recommendations [28], we have elaborated a panic diary, which tries to collect the maximum information on the patient's panic attacks. Daily, the patient records the following variables related to his/her panic attacks: situation, duration, whether it has been a panic attack or a high anxiety episode, whether it has been an unexpected panic attack or a conditioned one, what symptoms have appeared and their intensity, anticipatory anxiety, and severity of the attack.

3.1.2. Self-report measures

Our assessment protocol includes several self-reported measures which assess different clinical areas: a) measures directly related with panic disorder and agoraphobia; b) Measures related with general psychopathology (depression, anxiety and general symptoms); c) A self-report that measures functional impairment. The self-report instruments are the following:

Panic Disorder Severity Scale [31]**:** It is a clinician rated composite symptom scale for panic disorder. This scale includes ratings of frequency and distress of panic and

panic-like sensations (limited symptom episodes), severity of anticipatory anxiety, severity of situational avoidance, severity of impairment or interference in work and in social situations. In addition, there is one item rating phobic avoidance of physical sensations. Means for a PD sample (with mild or no agoraphobia) are 1.59 (SD= 0.43), for total scale, 1.83 (SD= 0.82) for frequency, 2.19 (SD= 0.61) for distress of panic, 1.94 (0.75) for anticipatory anxiety, 1.23 (SD= 0.65) for situational avoidance, 1.08 (SD= 0.58) for interoceptive avoidance, 1.29 (SD= 0.98) for work impairment, and 1.55 (SD= 0.82) for social impairment.

Anxiety Sensitivity Index [32]**:** It is a 16-item questionnaire that measures fear of anxiety. Each item expresses a concern about a possible aversive consequence of symptoms associated to anxiety. Items are rated on a 5-point scale. Means in a PD (with mild or no agoraphobia) was 32.1 (SD= 11.3) [33]. For nonclinical samples the mean score was 19.1 (SD= 9.11) [34].

The Mobility Inventory for Agoraphobia [35]**:** It is a 27-item questionnaire rated on a 5-point scale to assess agoraphobic avoidance behavior. The questionnaire evaluates the severity of the patient's avoidance, both when alone and when accompanied. Means for a PDA sample are 3.30 (SD= 0.99) when alone, and 2.41 (SD= 0.70) when accompanied, whereas for a normal control sample, means were 1.25 (SD= 0.24) and 1.07 (SD= 0.08) for alone and accompanied respectively.

Beck Depression Inventory [36]**:** This is one of the most widely used inventories for evaluating the presence of depressive symptoms. It is a 21-item self-report questionnaire. Scores of 10 or less are considered normative.

State-Trait Anxiety Inventory [37]**:** In this study only the 20-item Trait Anxiety Scale was used. The Anxiety Trait is defined as a relatively stable anxiety apprehension by which participants differ in their tendency to perceive situations as threatening and to increase, consequently, their state of anxiety. The scale has 20 items, half of them formulated in a positive way and the other half in a negative way. The score is shown on a four-point intensity scale. Oei, Evans & Crook [38] reports that the STAI-T in a PDA sample ranges from 51 to 54 and for those with PD ranges from 44 to 46.

Fear Questionnaire [30]**:** The FQ is a 24-item self-report measure that was designed specifically to monitor change in patients with phobias. Contains three five-item subscales (*agoraphobia, blood/injury,* and *social phobia)* a *global distress index* and a 5-item *anxiety/depression scale.* Means for a phobic sample are 47 (SD= 19.3) for the total phobia score, 17 (SD= 10.0) for agoraphobia, 15 (SD= 10.7) for blood/injury, 15 (SD= 8.5) for social phobia, 22 (SD= 9.1) for anxiety/depression, and 5.5 (SD= 2.7) for global phobic rating.

Maladjustment Scale [39]**:** This instrument assesses the degree of maladjustment the disorder causes in several areas of the participant's life. It consists in a 6-items scale rated from 0 to 5 where 0 = *Nothing* and 10 = *Very Much.* Means for a clinical sample is 18.04 (SD= 6.26), and for a normal sample 2.22 (SD= 1.66).

3.1.3. Specific measures to evaluate therapeutic effectiveness

We consider, in line with other researchers [40], that the following variables are important to determine the clinical significance of outcome in treatment effectiveness studies. These measures are related with the axis two or clinical utility axis of the clinical guide (*Template for Developing Guidelines: Interventions for Mental Disorders and Psychosocial Aspects of Physical Disorders*) that has been developed by the committee of experts of the *American Psychological Association* within the framework for "empirically valid treatments or treatments based on evidence" [9].

Therapist Global Impression: The therapist answers the question: *Considering your clinical experience, how do you evaluate the global severity of this patient?*, and evaluates from a clinical point of view the global impression about the patient's severity in a 1-6 subjective scale, where 1 = *Normal*, 2 = *Lightly disturbed*, 3 = *Moderately disturbed*, 4 = *Quite disturbed*, 5 = *Severely disturbed*, and 6 = *Very severely disturbed*. Adapted from Guy [41].

Expectations about exposure (EE): We have elaborated a questionnaire adapted from Borkovec and Nau [42] to measure the expectations about the virtual exposure treatment before starting it. The questions are about how logic the treatment is, to what extend it could satisfy the patient, if the patient would recommend this treatment to other people, if it could be useful to treat other problems, the usefulness for the patient's problem, and to what extend it could be aversive

Satisfaction with the exposure treatment (Se): We have also designed a questionnaire to assess the satisfaction with the exposure component. It screens the same aspects that the former questionnaire, but in this case it is fulfilled after the treatment completion. Adapted from Borkovec and Nau [42].

3.1.4. Assessment procedure

We established four assessment periods in order to test the efficacy and effectiveness of our treatment program: Pre-treatment assessment, post-treatment assessment after the completion of the treatment, and follow-up assessment, three and nine months after the completion of the treatment.

The pre-treatment assessment lasts two sessions summarized in table 1.

The post-treatment and follow-up assessment includes all the instruments, but the diagnostic interviews (screening and ADIS-IV).

3.2. Treatment protocol

3.2.1. Cognitive-Behavioral program for panic disorder

The program is a Cognitive behavioral program adapted from the most effective programs that are available [14, 17]. The treatment program include several components: a) Educational; b) Slow breathing training; c) Cognitive Therapy; d) Exposure; e) Relapse prevention. The treatment program includes nine sessions. The patients receive one session

Table 1. Assessment procedure

1ST SESSION (*video recorded for blind assessment*)
ADIS-IV. Consent form. *Homework:* Panic Attack Record, self-report questionnaires.
2ND SESSION
Collect and review self-report questionnaires. Target Behaviors: Fear, avoidance and belief in catastrophic thoughts. *Homework:* Panic Attack Record.
BLIND CLINICAL JUDGEMENT
Videotapes and assessment instruments will be given to an independent expert clinician who will make a clinical judgment.

per week for all components but exposure. The exposure sessions are carried out twice a week. The duration of the sessions is around one hour. The sessions are highly structured.

At the beginning of each session, the therapist presents the agenda with the contents that are going to be developed during the session. Due to the active role of patients throughout treatment, they can suggest the inclusion of additional topics related to panic in the agenda. All sessions finish with the assignment of homework. In the following paragraphs we describe briefly the treatment components.

EDUCATIONAL COMPONENT:

The main goal for the first session is to inform the patient about anxiety, fear, and panic.

The points to cover in the educational component are the following: a) The nature of anxiety, fear, and panic; b) Survival value of fear and anxiety; c) Anxiety and panic reactions are not dangerous; d) Three components of anxiety: physiological, cognitive, and behavioral; e) Important role of the cognitive component of anxiety; f) Cognitive model of panic; g) Treatment rationale.

SLOW BREATHING TRAINING:

We use one technique to treat the physiological component of panic and anxiety: breathing training. The points to cover in the introduction of this component are the following: a) Behavioral experiment: hyperventilation test; b) Role of hyperventilation in the development of a panic attack; c) Breathing training: Audio taped slow breathing rhythm (8-12 breathings per minute). Patient practices slow breathing training at the consultation room and as homework assignment. The goal is that the patient uses this technique to control the anxiety symptoms.

COGNITIVE THERAPY COMPONENT:

The goal of this component is to treat the cognitive component of panic disorder/agoraphobia. This component is introduced in the second session and practice along all the treatment. The content of this component is the following: a) Cognitive model of panic: From the cognitive model of panic, the important role of misinterpretation of bodily sensations is highlighted; b) Cognitive restructuring: Convenience of changing these misinterpretations to overcome panic attacks. The patient is trained in several cognitive restructuring techniques: Examining the evidence, challenging catastrophic thinking, rational self-statements, perspective taking.

EXPOSURE COMPONENT:

The main component of this treatment program is exposure. The main goal is to treat the behavioral component of panic disorder and agoraphobia.

The application of exposure was different in our study to test the efficacy of VR for the treatment of PDA. In our work we established two treatment conditions: Virtual Reality Exposure and In Vivo Exposure.

The main points to treat in the introduction of this component are: a) Advantages and disadvantages of avoidance; b) Exposure: definition and advantages; c) exposure rules; d) situational and interoceptive exposure; e) revision of target behaviors and planning of exposure sessions.This introduction is the same for the two different treatment conditions.

However, exposure is in VR in one of the treatment conditions and In Vivo in the other.

We carry out six exposure sessions without self-exposure instructions (VR *vs*. In Vivo) to control that the participants in the VR condition do not practice in vivo exposure at home. One way to control it is conducting two or more exposure sessions per week.

RELAPSE PREVENTION COMPONENT:

The main goal of this last component is to prevent future relapses once the treatment has finished. This component is carried out along the last session. The content of this component includes: Evaluation of the patient's improvement; review of the treatment components; improvement attribution to the different components; reinforcement to the patient's effort and achievements; evaluation of the belief in catastrophic thoughts; evaluation of fear/avoidance regarding target behaviors; expectations regarding panic attacks; need to generalize the learned skills to new sensations and situations; need to practice the learned skills; final evaluation of the treatment; setting of the post-treatment, and follow-up assessment meetings.

3.2.2. Step-by-step application of the treatment program

In this section we present the content of each treatment session, summarized in tables 2 to 8.

Table 2. Session 1 Schedule: Educational component

• What is anxiety?
• Adaptive value of anxiety.
• Absence of harmful consequences of anxiety.
• Anxiety responses (Threefold Response System).
• Central role of thoughts in the triggering of anxiety.
• Cognitive model of panic attacks.
• Hyperventilation test.
• Role of hyperventilation in panic attacks.
• Homework assignment: recording the catastrophic interpretations taking place along the week during panic attacks, and the degree of conviction.

Table 3. Session 2 Schedule: Slow breathing training and cognitive therapy

• Solving patient's doubts on the cognitive model of panic disorder and the role of hyperventilation in the crises.
• How to broke down the vicious circle of panic.
• Slow breathing training (seated or lying down).
• Introducing cognitive therapy.
• Cognitive discussion of any of the catastrophic interpretations of the most frequent bodily sensations during the crises.
• Homework assignment: practicing slow breathing (twice a day for half an hour each).

Table 4. Session 3 Schedule: Exposure to internal and external stimuli:

IN VIVO TREATMENT CONDITION
• Revision of some of the avoided sensations or situations. Disadvantages of avoidance.
• Introduction of exposure: definition and advantages.
• Rules to perform exposure
• Review of target-behaviors and design of a hierarchy
• Example of exposure task to a feared situation or sensation

Table 5. Session 3 Schedule: Exposure to internal and external stimuli:

VR TREATMENT CONDITION

- Revision of some of the avoided sensations or situations. Disadvantages of avoidance.
- Introduction of exposure: definition and advantages.
- Rules to perform exposure.
- Review of target-behaviors and design of a hierarchy.
- Training in VR.
- Example of exposure task to a feared situation and/or sensation using virtual reality.

Table 6. Sessions 4 to 8 Schedule for IN VIVO TREATMENT CONDITION:
Exposure to internal and external stimuli, and cognitive discussion without self-exposure instructions

- Revision of exposure hierarchies and of cognitive restructuring.
- In-session exercises of exposure to internal sensations.
- In-session tasks of In Vivo exposure to external stimuli.
- Cognitive discussions of catastrophic interpretations.
- Homework assignment: Panic Record. No self-exposure instructions.

Table 7. Sessions 4 to 8 schedule for VR TREATMENT CONDITION:
Exposure to internal and external stimuli, and cognitive discussion without self-exposure instructions

- Revision of exposure hierarchies and of cognitive restructuring.
- In-session exercises of exposure to internal sensations and external stimuli (at the same time) using VR.
- Cognitive discussions of catastrophic interpretations.
- Homework assignment: Panic Record. No self-exposure instructions.

Table 8. Session 9 Schedule: Relapse prevention

- Appraisal of the patient's evolution along therapy.
- Review of the content of the past sessions.
- Examination of the patient's attribution for improvement.
- Reinforcement on the therapist's part.
- Assessment of the residual belief in the catastrophic interpretations of bodily sensations.
- Assessment of the residual degree of fear and avoidance of particular situations and sensations.
- Examination of the patient's expectations regarding having future crises.
- Stressing of the convenience of continuous practice to generalize what has been learned in therapy to other bodily sensations, different to the habitual ones, which could appear in future panic attacks.
- Convenience of continuing practicing the techniques learned.
- Final appraisal of therapy.
- Setting the post-test and follow-up sessions.

4. The use of virtual reality in the clinical protocols

4.1. Technical characteristics of virtual environments

The VEPSY Virtual Environments (VE) have been developed with Virtools Dev 2.0. The devices used are a PC. The features required are: Pentium II or equivalent, 64 MB of RAM, CD-ROM drive, a monitor capable of displaying 1024 by 768 in 16 bit color (65536 color / Hi-Color), a Direct3D or OpenGL compatible 3D Graphic Accelerator Card with 8 MB of

RAM, a Pointing Device (Mouse, etc.), and a Sound Card. The software required is Microsoft Windows (95, 98, ME, 2000 or NT 4.0 (with Service Pack 6), Microsoft Internet Explorer 4.0 or higher, and Microsoft DirectX 5.0 or higher for DirectX compatible 3D Graphic Accelerator Cards. As for the visual devices we use a V6 (*Virtual Research*) HMD (Head Mounted Display) as the patient visual device, and a 17" Monitor as the therapist visual device. The Navigation & Interaction Devices are a mouse (2 Buttons) as the patient navigation & interaction device, and a Keyboard as the tharapist interaction device. The Audio Devices are the V6 Headphones as the patient audio device, and Headphones as the therapist audio devices.

Our VR program is called Panic-Agoraphobia. It has four Virtual Environments. In each virtual scenario exposure to external and internal stimuli can be carried out simultaneously. We can simulate several bodily sensations: heart palpitations, short of breath, blurred vision and tunnel vision. Also, in each scenario we can use several modulators to graduate the difficulty of the situation (number of people, threatening conversations, length of the trips, etc.).

The first scenario is a training room. This is the starting situation in which the patient will find himself/herself when he/she enters the scenario. Basically, the user must practice three things: a) *Movement within the Virtual Environment, b) Detection of Interactive Objects, c) Interaction with objects.*

Scenario 2 "The Room": This scenario is an environment of anticipatory anxiety where the user finds him/herself in a typical living room. In this room, it is possible to interact with the following objects:

Music player: The music player can be turned on or off (depending of the current status). When turned on, several commercial announcements can be heard about the starting of big sales in a mall.

Answering Machine: The answering machine is an interactive object which can be used with the left button (*one click*) of the mouse, capable of reproducing up to four different messages. Each of them presents a demand to shop certain objects, with different degrees of difficulty. When the activity at the room has finished, it's possible to go outside.

Scenario 3 "The Subway": In the starting situation the patient finds him/herself in a subway station, where a group of passengers is waiting for the arrival of the subway.

When the patient moves towards the edge of the platform and the psychologist presses a key, the subway arrives. At this point, it is possible to select the number of passengers coming inside the subway. Then, the patient must climb on the subway through any of its doors. Once inside, the psychologist may select if he/she desires any other passenger to climb on the subway. Once inside the subway, the psychologist may start the machine. The duration of the trip between the two stations is unlimited, and will only end if at the psychologist will. In this virtual environment, the psychologist can bring about the Heart Rhythm and Breathing Sound effect. This effect will play a sound that will simulate the patient's heart rhythm and breathing. This sound will have three levels that will represent several frequencies: Paused, Middle and Accelerated.

Scenario 4: "The Shopping Mall": This scenario is an environment that re-creates a Shopping Mall. The Mall is composed of one level – Ground Level -where books and music CDs are available.

The starting situation opens with the user inside the scenario of the Shopping Mall, at the entrance to the ground level. Starting from this position, he/she may move throughout the whole scenario. When reaching a couple of shelves the user may access to different interactive objects, like a book or a CD.

If the user wants to approach to the cashier to pay the objects he/she has grabbed, it's sufficient to come close to it, and position in the line. In the line there are 3 people and the patient is the last in line. The line will only advance when the psychologist wants.

When any of these persons are paying, the psychologist can bring about a trouble situation. This situation consists in the credit card giving problems, which makes the wait to become longer. When all the people have abandoned the line, it is the patient's turn.

Now he has to pay. In this situation, the psychologist can also cause the trouble situation mentioned previously. Once the trouble situation has ended, the objects will disappear and a paper bag will appear instead.

Another trouble situation that can be generated before or after buying is to provoke a blocking at one of the aisles. When the user goes through the aisle, more people walking will appear, blocking the way out. In the Shopping Mall, the psychologist can also bring about the Heart Rhythm and Breathing Sound effect.

4.2. The use of virtual environments in the treatment protocol

It is important to remind patients that VR allows them to "feel and experience" what happens when coping with a phobic situation, but in a completely safe context.

Patients should be introduced to the system at the first session with a brief explanation of what they are going to do and what they will encounter. For example: "Have you used a computer? Have you ever played a computer game? Have you heard of VR? What we are going to do is very similar. You are going to sit in front of the computer. You will wear this headmounted display and use the mouse. With VR you won't just see a computer screen, you will be "inside" the screen. You will see some rooms or settings where there are different things. The first room is used for training in order to get used to the system. In this room you will learn how to move and interact with the objects. You will encounter different situations as the sessions progress. The advantage of VR is that you are going to do things you don't like or are afraid to do in the real world as well as things that cannot be done in the real world. This means that you can practice the activities you find difficult to perform in the real world. The most important part is that you will not be alone there because I will be with you all the time. We will be in the same settings and situations together. It's a great opportunity to do all the things you normally avoid. Is there anything you would like to know before we begin?"

It is very important to help patients get inside the situation. Therapists must be careful to contextualize the environments, adapting them to aspects of daily living with short introductory stories ("you are in the bedroom in the apartment you've rented"), speaking in the present tense ("walk around, take a good look at all the furniture"), and stress that the patient is actually experiencing all that is happening in the virtual environment "now".

The context and all the things that can happen should be explained briefly before each new situation. For instance, the sounds or movements the system makes: what's happening? What do you think that noise means?

5. Large-scale clinical trial

As we have already mentioned in this chapter, we have carried out a study to offer data about the differential efficacy and effectiveness of Virtual Reality exposure vs. In vivo exposure in the treatment of panic disorder and agoraphobia. In this section we describe briefly the study and the results obtained.

5.1. Experimental design

To achieve the main goal of our research we will compare the effectiveness of several control and experimental conditions. We established one control condition, a Waiting List (WL). The patients in this condition were assigned to the treatment conditions afterwards.

We established 2 experimental or treatment conditions. One of the treatment conditions was a cognitive-behavioral program that includes VR as the exposure component (VRE).

The other treatment condition was a cognitive behavioral program that includes In Vivo as the exposure component (IVE).

The procedure to carry out this experimental design is as follows:

In a first intake we contacted possible participants who meet DSM-IV [7] of PDA among people who asked for help in Jaume I University Anxiety Disorders Clinic or among people referred to our clinic by other mental health professionals.

The patients were assigned to the WL control condition or to one of the two treatment conditions: VR or In vivo exposure. All patients were assessed at pre-treatment.

Then, patients in the treatment conditions started the treatment that lasted about six to eight weeks. Then they were assessed at post-treatment and at 3-month and 9-month follow-up.

The patients in the WL waited six to eight weeks without being treated. Then, they went through a second assessment and they were assigned to one of the treatment conditions.

5.2. Participants

The sample was initially composed by fifty people who met DSM-IV [7] criteria for panic disorder with or without agoraphobia. Three participants dropped out during the assessment phase. The rest, forty seven, started the treatment. Seven patients improved after the first treatment component, the educational component. They were not included in the comparison between VR exposure and in vivo exposure. Therefore, the final sample was composed by forty patients who were randomly assigned to three experimental conditions: 1. Waiting list control: 12 patients; 2. In vivo exposure treatment: 14 patients; 3. VR exposure treatment: 14 patients.

Patients in the waiting list condition were assigned to the treatment conditions after the waiting list phase: Eight have completed the waiting list phase and have been assigned to the treatment conditions, although they have not completed the treatment yet. Four are still in the waiting list phase.

Three more patients initially assigned to the treatment conditions have not completed the treatment yet.

Twenty five patients have completed the follow-up assessment in different moments: we have data so far of 11 patients at three-months follow-up, data of 10 patients at six months follow-up, and data of four patients at nine-months follow-up.

In table 9 and 10 we present the sample description (N = 40) attending to demographic and clinical features.

5.3. Assessment

A detailed description of the assessment protocol and procedure can be found in section 3.1. of this chapter.

Table 9: Demographic features

	Mean (SD) or (%)
Age	33.74 (11.80)
Gender	
Males	27.5%
Females	72.5%
Marital status	
Single	32.4%
Partnered	13.5%
Married	51.4%
Divorced	2.7%
Educational status	
Elementary school	21.6%
High school	43.2%
College	35.1%

Table 10: Clinical features

	(%)		(%)
Diagnosis		Comorbidity Axis II	
PD	15.4%	YES	8.1%
PDA	79.5%	NO	91.9%
AG	5.1%		
Comorbidity: Axis I		Medication	
YES	29.7%	Non	38.2%
NO	70.3%	Antidepressants	5.9%
		Anxiolytics	41.2%
		Both	14.7%
Secondary diagnosis axis I		Clinical status (severity) rated by	
Other anxiety disorder	44.44%	therapist at pre-treatment	
Mood disorder	44.44%	Mild	16.7%
Hypochondriasis	11.11%	Moderate	43.3%
		Severe	26.7%
		Very severe	10%

PD: Panic disorder; PDA: Panic disorder with agoraphobia; AG: Agoraphobia without history of panic disorder.

5.4. Treatment

The treatment lasts nine sessions. Given that the main goal of this trial is to show data about the use of the exposure component (comparing in vivo exposure vs. VR exposure) we have focused in the exposure component. A more detailed description of the treatment can be found in section 3.2. of this chapter.

5.5. Results

In this section we will summarize very briefly the results obtained in the large-scale clinical trial conducted in the VEPSY project so far. A more detailed description of the final results can be found in Botella, Villa, Garcia-Palacios, Banos, Quero, Alcaniz & Riva (submitted) [43].

Regarding the measures related to the axis 1 or efficacy axis, our data so far showed that VR exposure and in vivo exposure achieved a similar efficacy and both were significantly more efficacious than the waiting list group in measures directly related to panic disorder and agoraphobia, general psychopathology, and impairment.

As for the measures related to the axis 2 or effectiveness axis, both treatment conditions seemed equally effective regarding the expectations and satisfaction related to

the exposure component, the improvement rated by both the clinician and the patient, and the clinical status evaluated by the clinician.

5.6. Discussion

In this section we will discuss briefly the results of our large-scale clinical trial. We will do so taking into account the clinical guide (*Template for Developing Guidelines: Interventions for Mental Disorders and Psychosocial Aspects of Physical Disorders*) that has been developed by the committee of experts of the *American Psychological Association* within the framework for "empirically valid treatments or treatments based on evidence" [9]. This guide recommends to consider two "Axes": the efficacy Axis, or axis of internal validity, which entails analyzing the scientific evidence that is available for any given intervention, and the effectiveness, or clinical utility Axis, which entails analyzing the possibility of the intervention in the specific context in which it has to be offered [12, 13].

With regard to the efficacy axis, our data suggest that VR exposure and in vivo exposure showed more efficacy than a waiting list control group in the treatment of panic disorder and agoraphobia. Both treatment groups showed a significant improvement in all measures comparing with the control condition. The two treatment conditions showed a similar efficacy. There were no significant differences between VR exposure and in vivo exposure in measures directly related with panic disorder and agoraphobia:

As for the measures regarding effectiveness, that is, those measures more related with clinical utility, both treatment groups were equally effective regarding expectation and satisfaction with the exposure component. Also, clinicians rated the global clinical state of the patients and the improvement achieved similarly in both treatment conditions. The patients also rated their improvement similarly in the VR group and the in vivo group.

6. Conclusions and future directions

The main conclusion of our large-scale clinical trial is that we have developed an exposure component using VR that shows a similar efficacy and effectiveness than the exposure component of choice for panic disorder and agoraphobia: in vivo exposure.

As we have already mentioned, VR exposure presents several advantages compared with conventional in vivo exposure to treat panic disorder and agoraphobia. In in-vivo exposure patients undergo graded exposure to what they fear most with the help of a psychologist. In comparison with this type of technique, in VR the therapist can control the feared situations at will and with a high degree of safety for the patient, as it is easier to grade the feared situations. Another advantage is that VR is more confidential because treatment takes place in the therapist's office, and patients need not fear "making a spectacle of themselves" in public or simply that their problem might be known. Besides, it is much cheaper as it takes place in the therapist's office, and considering the wide number of situations and activities that agoraphobic patients use to avoid, VR can save time and money significantly.

Another advantage of our VR exposure program for the treatment of panic disorder and agoraphobia is the possibility of doing VR interoceptive exposure. Interoceptive exposure consists of exposing patients to bodily sensations similar to the ones experienced in their panic attacks. This can be achieved carrying out several tasks in the consultation room, such as hyperventilate, jumping, blowing through a straw, running, etc. VR could be

a more natural setting for interoceptive exposure than the consultation room because we can elicit bodily sensations while the patient is immerse in VR agoraphobic situations.

Finally, we think that VR exposure can be a useful intermediate step for those patients who refuse in vivo exposure because the idea of facing the real agoraphobic situations is too aversive for them. We think that making those patients go through a VR exposure treatment can increase the likelihood that they accept an in vivo exposure program afterwards.

All this advantages has guide our work regarding the design and testing of a VR exposure program for panic disorder and agoraphobia. Our data support that our VR program achieved a significant improvement in important panic disorder and agoraphobia measures. The treatment was also effective, that is participants and therapists showed a good acceptance and satisfaction related to the VR exposure component.

There is some more research to be carried out after these findings. We would like to highlight the next steps to follow:

1. Complete the treatment and assessments of all the participants.
2. Wait for the one-year follow-up assessment to state that our VR exposure component is effective at long-term.
3. During this project we have designed a telepsychology program, to assist the virtual reality exposure program, but we have not tested its use and its effectiveness in the treatment of panic disorder and agoraphobia yet. One of our future research aims is to test the efficacy and effectiveness of this tool.

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