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The Use of Biofeedback in Clinical Virtual Reality: The Intrepid Project

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Abstract. In our protocol for the treatment of Generalized Anxiety Disorders we use Virtual reality (VR) to facilitate emotional regulation and the relaxation process. Using a biofeedback biomonitoring system (GSR, HR, Thermal) the patient is made aware of his or her reactions through the modification of some features of the VR environment in real time. Using mental exercises the patient learns to control these physiological parameters and using the feedback provided by the virtual environment is able to gauge his or her success. To test this concept, we planned a randomized controlled trial (NCT00602212) , including three groups of 15 patients each (for a total of 45 patients): (1) the VR group, (2) the non-VR group, and (3) the waiting list (WL) group.

Keywords: Virtual Reality, Generalized Anxiety Disorders, Biofeedback, Intrepid project

Introduction

Generalized anxiety disorder (GAD) is a psychiatric disorder characterized by a constant and unspecific anxiety that interferes with daily-life activities. Its high prevalence in general population and the severe limitations it causes, point out the necessity to find new efficient strategies to treat it. Together with the cognitive-behavioral treatments, relaxation represents a useful approach for the treatment of GAD, but it has the limitation that it is hard to be learned [1-3].

Traditionally, relaxation techniques are verbally taught by a therapist or recorded on an audiotape, while recently a series of CDs of calming music have been used to help individuals to relax themselves, showing positive effects on anxiety reduction by achieving psychological benefits including distraction and sense of control over symptoms. These CDs strengthened the positive effect of calm and sedative music with relaxation techniques to achieve enhanced effects. To increase effectiveness, commercial relaxation DVDs also integrated visual stimuli. In this approach, the visual representation of the scenario supports the process of relaxation creating an isolated context in which the subject can feel to stay.

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1. Methods

1.1 Virtual reality and Biofeedback

In our protocol Virtual reality (VR) is used to facilitate relaxation processes in stressed or anxious subjects by visually presenting a relaxing environment. The advantage of VR compared to relaxing CDs or DVDs is its ability to induce a sense of presence in the users, which is defined as the "feeling of being in a world that exists outside of the self " [4-6]. The visual presentation of a virtual calm scenario can facilitate patients' practice and mastery of relaxation, making the experience more vivid and real than the one that most subjects can create using their own imagination and memory, and triggering a broad empowerment process within the experience induced by a high sense of presence. [7-8].

More, using a biofeedback biomonitoring system (GSR, HR, Thermal) the patient is made aware of his or her reactions through the modification of some features of the VR environment in real time. Using mental exercises the patient learns to control these physiological parameters and using the feedback provided by the virtual environment is able to gauge his or her success.

2. Materials

The virtual environment used in this project is designed as a tropical island facing on the ocean and containing a forest on its internal area. Patients can explore the island starting from the beach, which is the arrival point, reached by a boat. Following a footpath that guides through the forest, one can arrive to the start point, where different panels are represented to indicate the directions to go in order to reach the different clinical areas (figure 1). In each clinical area a relaxation exercise is arranged, that combines the virtual scenario and the biomonitoring system. In fact, the main feature of this training is that some elements of the virtual environment are directly modified by the physiological parameters recorded on real time on the patient. Thus, the patient receives an immediate feedback on his/her level of activation (as in traditional biofeedback techniques), but with the surplus value given by the physical environment that he/she is immersively exploring. The elements of the island that are triggered by patient's biological parameters are the following:

- Waves: the reduction of the physiological arousal corresponds to a reduction of the waves until the ocean becomes completely calm;
- Campfire: physiological parameters control the fire intensity, so that the reduction of activation results on reduction of the fire until it goes out;
- Clouds: the sky ranges from cloudy to completely clear and sunny (see figure 2);
- Waterfall: the reduction of the physiological arousal corresponds to a reduction of the stream intensity until the water stops.

One of the exercises is customizable by the therapist, who can choose words or images that remind the patient something stressful. This technique serves as a stress inoculation program, and the patient can experience the reduction in size –fading-floating- of the chosen item, depending on his/her ability to relax himself.

Figure 1. A screenshot of the island.

Figure 2. The different looks assumed by the sky depending on the physiological parameters

2.1. Procedure

To test the efficacy of the proposed approach we are going to set up a randomized controlled trial [9]. Patients who will enter the study must meet the DSM-IV criteria for Generalized Anxiety Disorder (GAD), and will be selected after a psychological interview, that will include a clinical evaluation with the administration of the following semi-structured questionnaires:

- PSWQ (Penn State Worry Questionnarie);
- BAI (Beck Anxiety Inventory);
- STAI – Y2 (State-Trait Anxiety Inventory);
- HARS (Hamilton Anxiety Rating Scale);
- GAD -7.

The study will include three groups of 15 patients each (for a total of 45 patients):

1. VR+BF: in this experimental condition patients will receive a treatment based on virtual reality, combined to biofeedback. Relaxation will be induced by

navigation on a virtual environment in which patient may move and interact, following auditory narratives that support images. A wearable biosensor system will provide suggestions to the therapist based on the reactions of the patients, and the biosensor data will directly modify the virtual reality experience in real time.

2. VR: in this experimental condition patients will receive a treatment based on virtual reality. Relaxation will be induced by navigation on a virtual environment in which patient may move and interact, following auditory narratives that support images. In this condition, the critical environment points that in the VR+BF condition were modified on the basis of biosensors activity, will be set on the lowest parameter and will not be modifiable by physiological parameters of the patient.
3. WL: this is a control condition, in which patients will be included in a waiting list and will not receive any kind of treatment.

Groups VR+ BF and VR will participate to 8 training sessions, each consisting in relaxation procedures consistent with the experimental target (virtual reality combined with biofeedback vs. virtual reality alone). The experimental groups, thus, will differ only on the basis of feedback used to induce relaxation.

In order to improve the efficacy of the training and to increase the effects of relaxation, patients will practice relaxation techniques outside therapist's office by experiencing a Homecare Scenario. This will be realized by presenting on a mobile device a non-navigable version of the same virtual environment experienced during the therapy.

Patient candidates to enter this study will be evaluated in the first session with therapist, in which they will undergo the psychological questionnaires described above.

Those patients, who will meet the inclusion criteria, then will start the 8-sessions relaxation program.

Relaxation programs, regardless the instruments used, will differ along the sessions, following this schema:

- the first six sessions are dedicated to relaxation of different body parts, one each 2 sessions;
- during the 7th and 8th sessions a stressful element will be included (patients will be asked to describe a particular stressful event of their life in order to induce a high level of stress). This event will be visualized in both the experimental conditions using images or key words that remind to it. After that, they will be encouraged to apply the learned techniques to relax themselves.

In this experiment we will use as dependent variables, to quantify the anxiety's level modification, both psychological and psychophysiological measures.

Psychological assessment: each patient will undergo a series of psychometric questionnaires that will give us a quantitative measures of his anxiety. These evaluation will be administered at the beginning and at the end of each training session:

- STAI Y1 (State-Trait Anxiety Inventory);
- VAS-A (Visual Analogue Scale for Anxiety).

Psychophysiological assessment: several physiological parameters (skin conductance response – SCR, heart and respiratory rates, muscle tension) will be registered during the treatment session, in order to obtain and monitor in vivo measures of emotional state of patients who belong to the experimental groups.

3. Expected results

Since Virtual Reality is known to be effective to induce relaxation, the first expected result is a bigger reduction of anxiety level in patients belonging to the two experimental groups, if compared with the control group.
More interestingly, our hypothesis is that the combination of virtual reality and the special kind of biofeedback used (which is able to directly modify the virtual environment) will result in better and faster relaxation learning, compared with virtual reality alone. If so, this new instrument to treat anxiety disorders could be applied and tested even in other anxiety-related pathologies.

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