

The Intrepid Project – Biosensor-Enhanced Virtual Therapy for the Treatment of Generalized Anxiety Disorders

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Abstract. Generalized anxiety disorder (GAD) is a psychiatric disorder characterized by a constant and unspecific anxiety that interferes with daily-life activities. Together with the cognitive-behavioural treatments, relaxation represents a useful approach for the treatment of GAD, but it has the limitation that it is hard to be learned. To overcome this limitation we propose the use of biofeedback enhanced virtual reality (VR) to facilitate the relaxation process. The VR relaxation experience will be strengthened by the use of a mobile phone able to track and visualize, in an outpatient setting too, the physiological data of the patients. To test this concept, we planned a randomized controlled trial (NCT00602212), including three groups of 15 patients each (for a total of 75 patients): (1) the VR group, (2) the non-VR group and (3) the waiting list (WL) group. This controlled trial will be able to evaluate the effects of the use of VR in relaxation while preserving the benefits of randomization to reduce bias.

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

1. 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-behavioural 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]. Even if relaxation represents a useful approach for the treatment of GAD, it presents an important limitation: it is difficult to be learned.

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.

2. Methods

2.1. The Advantage of Virtual Reality (Inpatient Scenario)

In our protocol Virtual reality (VR) is used to facilitate relaxation processes in stressed or anxious subjects by visually presenting a relaxing environment (an island or a lake). The advantage of VR compared to relaxing CDs or DVDs is its ability to induce a sense of presence in the users, that 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].

2.2. The Use of Biosensors (Inpatient Scenario)

A knowledge-based biomonitoring system will allow for the adaptation of the virtual reality environment in real time. The patient is made aware of his or her reactions to the VR environment through a number of sensors attached to his or her body (GSR, HR, Thermal, EMG, see Figure 1). Using mental exercises the patient learns to control these functions and using the feedback provided by the sensors is able to gauge his or her success.

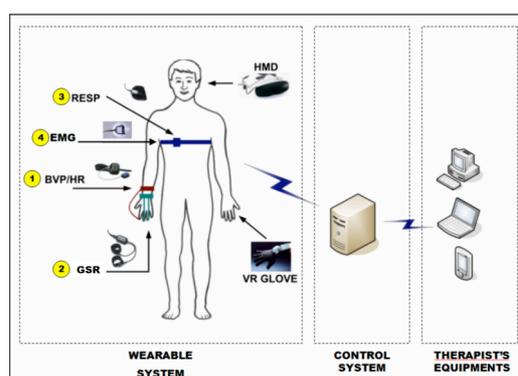


Figure 1. The technology used by the Intrepid Project (inpatient scenario)

Specifically, physiological responses will control/modify the following features of the virtual environment:

- *Waves*: when the subject reaches one of the clinical areas previously chosen by the therapist (the palm, the gazebo, or the sun chair), the ocean will become slighted. From the moment in which the subject reaches the target point his/her physiological parameters will control the waves. The reduction of the

physiological arousal will correspond to a reduction of the waves until the ocean becomes completely calm;

- *Clouds*: when the subject reaches one of the clinical areas previously chosen by the therapist (the palm, the gazebo, or the sun chair), the sky will become slighted. From the moment in which the subject reaches the target point his/her physiological parameters will control the clouds. The reduction of the physiological arousal will correspond to a reduction of the clouds until the sky becomes clear and sunny;
- *Campfire*: when the subject reaches the campfire, the fire will become higher. From the moment in which the subject reaches the target point his/her physiological parameters will control the fire' intensity. The reduction of the physiological arousal will correspond to a reduction of the fire' intensity until the fire goes out;
- *Water*: when the subject reaches the waterfall, the stream of water will be stronger. From the moment in which the subject reaches the target point his/her physiological parameters will control the stream of water. The reduction of the physiological arousal will correspond to a reduction of the stream intensity until the water stops;
- *Clinical targets*: clinical targets are words or objects (.jpeg; .gif) chosen by the therapist on the basis of the anxious contents expressed by the subject during a preliminary session (i.e. the word FEAR, DEATH, ILLNESS; the image of a car accident, boss, office, etc). The subject will be asked to reach the clinical area and the clinical target will come out from it. Again, the physiological parameters will control the events. Expected effects selectable by the therapist:
 1. *Reduction in size*: the word/object will be progressively smaller;
 2. *Fading*: the word/object will be progressively more transparent;
 3. *Floating*: the word/object will fly away;
 4. *Burning*: the word/object will burn in fire and disappear;
 5. *Morphing*: the word/object will change in a different one.

The activation of waves, clouds, campfire, water and clinical targets are controlled by the therapist through the keyboard also during the session

2.3. The Use of Biosensors (Outpatient Scenario)

A significant part of any relaxation protocol requires homework and home training. However, a critical issue related to the use of virtual exposure in the treatment of anxiety related disorders is *the lack of availability of a Virtual Reality system in the real life context of the patient*: both the cost and the setting of the system limit its use to the health care centre/hospital/therapist's office. The solution suggested by the project is the use of a *mobile exposure system* (Figure 2) able:

- To present and structure emotionally relevant contents in a home setting.
- To verify the compliance of the patient and eventually alert patient/therapist;
- To track in real-time the emotional level of the patient and record it for later assessment by the therapist;
- To provide a feedback to the patient able to help him in coping with the contents;
- To automatically contact the therapist if the emotional level is higher than a preset cut-off value defined by the therapist.

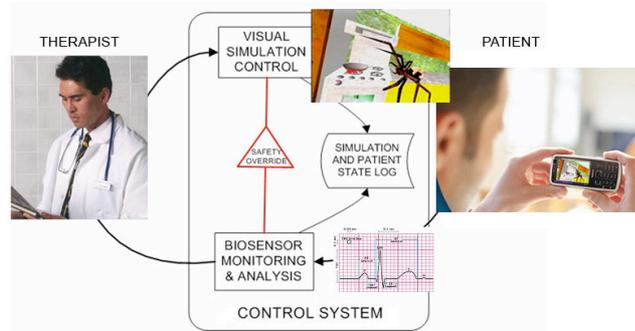


Figure 2. The technology used by the Intrepid Project (outpatient scenario)

The Hardware will consists of:

- *Multimedia Mobile Phone with video out capabilities:* HTC Touch Pro (800€ without contract). It has Bluetooth, and Windows Mobile Professional 6.1 OS.



Figure 3. HTC Touch Pro

- *Head-Mounted Display:* Zeiss Cinemizer (370€) or Myvu Cristal (270€). Both have video input, can be worn with glasses and offer VGA resolution.



Figure 4. Zeiss Cinemizer (left) and Myvu Cristal (right)

- For physiological measurements, we will use a portable bluetooth biosensing system developed by the project.

Different videos (non-interactive navigation) of the virtual environment and the associated relaxing narratives will be experienced by the patients during their “home

training". While they watch the videos, their physiological parameters will be recorded and elaborated by the cell phone. Patients will receive a simple feedback:

- *Unspecific feedback:*
 - *Bar:* a moving bar will provide a feedback about the data from biosensors;
 - *Pulsating ball:* a pulsating ball will provide a feedback about the data from biosensors;
 - *Raising butterfly:* a butterfly, raising to the top of the screen, will provide a feedback about the data from biosensors;
 - *A blooming flower:* a flower, blooming slowly, will provide a feedback about the data from biosensors.

- *Specific feedback:*

The patient can input some text or select an image. Expected feedbacks selectable by the patient:

 - *Reduction in size:* the text/photo will be progressively smaller;
 - *Fading:* the text/photo will be progressively more transparent;
 - *Floating:* the text/photo will fly away.

3. Controlled Trial

To test the efficacy of the proposed approach we are going to set up a randomized controlled trial [9]. The study will include 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. Patients in the VR group will be taught to relax using a VR relaxing environment and audio-visual mobile narratives; patients in the non-VR group will be taught to relax using the same relaxing narratives proposed to the VR group, but without the VR support, and patients in the WL group will not receive any kind of relaxation training. Psychometric and psychophysiological outcomes will serve as quantitative dependent variables, while subjective reports of participants will be used as qualitative dependent variables.

4. Conclusions

The use of biofeedback-enhanced relaxation-oriented VR may represent a promising approach in the treatment of GAD: it may enhance the quality of the relaxing experience through the elicitation of the sense of presence. Our hypothesis is that VR will allow an enhancement of traditional biomonitoring methods through the immersion of the patient in the process. To test this hypothesis we planned a controlled trial [9] that will start in the next months

5. Trial Registration

NCT00602212 (ClinicalTrials.gov)

6. Acknowledgments

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7. References

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