Development of virtual reality-based exposure techniques for improving anorexia nervosa treatment

1. Objective of the study

Anorexia nervosa (AN) is a severe eating disorder that usually begins during adolescence and often persists into adulthood. Studies suggest that less than 50% of patients reach full remission of symptoms, with full recovery being very difficult after 10 years of onset. Unlike other eating disorders, there is no evidence-based treatment of choice for AN, and interventions, including cognitive-behavioral therapy, often achieve modest results. Therefore, it is necessary to develop new intervention techniques that enhance the effectiveness of treatments and facilitate achieving the objectives of normalization of weight and eating patterns. One of the greatest difficulties in achieving these objectives is the extreme fear of weight gain and becoming obese, which is characteristic of patients with AN and which produces great resistance to normalisation of intake. Body exposure has been proposed as an effective technique for the habituation of the anxiety response to the own body and the reduction of associated avoidance behaviors like dietary restriction. Virtual reality technology offers the possibility of taking body exposure therapy one step further, allowing the patient to experience the illusion of ownership of a virtual body that progressively increases its weight to reach a healthy body mass index (BMI).

The objective of this research is the development of an empirically validated virtual reality-based body exposure technique that allows the systematic and hierarchical exposure of the patient to a virtual representation of his or her own body that increases in weight throughout the exposure sessions until a healthy BMI is reached. It is expected that the extinction of the anxiety response generated by exposure to such virtual representation will be enhanced by the inclusion of techniques for producing an ownership illusion of the virtual body, improving the emotional, cognitive and behavioral response of the patient to his body image and facilitating the achievement of treatment objectives.

In accordance with this general objective, the following specific objectives are proposed:

a. To develop an intervention program for AN based on body exposure therapy through virtual reality, which allows gradual exposure to a virtual representation of the body itself with different BMI increments, in order to extinguish the anxiety response to body image and the fear of gaining weight.

b. To evaluate the effectiveness of the program developed through a randomized controlled clinical trial in which participants will be evaluated before starting treatment, at the end of treatment and after a follow-up of six months.

c. To evaluate the attentional patterns of patients with AN towards the virtual representation of their own body before and after the end of the treatment.

d. To compare the attentional patterns towards the virtual representation of the own body of patients with AN according to the treatment received.

In order to achieve these objectives, a randomized controlled clinical trial will be conducted to evaluate the efficacy of the addition of a body image exposure component using Virtual Reality to the usual treatment. After signing informed consent, patients will be randomly assigned to one of the two groups 1) Virtual Reality Exposure (VR) added to the usual cognitive behavioral therapy (CBT) or 2) the usual CBT treatment only (as a control condition). Data will be collected before, during and at the end of the intervention, as well as after six months of follow-up. At the end of the study, if the experimental treatment demonstrates its efficacy, it will be offered to patients in the control group.

1.1. Hypotheses

The starting hypothesis of the project is the following: if a component of body exposure through virtual reality (experimental group) is added to the usual cognitive-behavioral treatment of AN, intensified through the production of ownership illusion of the virtual body, then the treatment will be more effective than applying conventional cognitive-behavioral treatment only (control group).

Specifically, these more specific hypotheses are posed in relation to specific objectives a) and b):

- The experimental group (CBT+RV) will show a significant increase in BMI values, with respect to the control group (CBT), after comparing BMI values before and after treatment.

- The experimental group (CBT+ RV), will show a significant reduction of the levels of body-related anxiety, fear of gaining weight and body image disturbance, with respect to the control group (CBT), after comparing measures before and after the treatment.

The third hypothesis is posed in relation to the specific objectives c) and d), which are intended to evaluate the attentional bias that AN patients show towards their body, compared with a non-clinical sample of adolescents before the intervention. Based on previous literature, it is expected that:

- Patients in the experimental group (CBT+RV) will show a significantly greater reduction in attentional bias towards weight-related body parts compared to the control group (CBT) after comparing pre-treatment and post-treatment measures.

2. Participants

Patients with a primary diagnosis of anorexia nervosa (DSM-5) from 14 years of age and with BMI<18.5. Participants will mainly be recruited from the Eating Disorders Unit of the Hospital Sant Joan de Déu in Barcelona.

2.1. Inclusion and exclusion criteria

The following inclusion criteria are applied: patients with a primary diagnosis of anorexia nervosa (DSM-V criteria), from 14 years of age and with BMI < 18.5. Subsyndromic patientanorexia criteria, with the exception of a maximum of two, will also be included. At the beginning of the study, an attempt to complete the entire sample with adolescent patients between the ages of 14 and 18 will be made.

The exclusion criteria taken into account are: serious mental disorder, visual deficits that prevent exposure, epilepsy, pregnancy and clinical cardiac arrhythmia.

2.2. Sample size

Given the novelty of the intervention, there are no published studies in which the effectiveness of virtual reality exposure to progressive increases in body weight of the virtual body has been compared with other treatments for AN. Therefore, in order to establish the sample size from the expected effect size, recent randomized controlled studies that applied exposure therapy to the current body image have been considered. In this line, Hildebrandt et al (Hildebrandt, Loeb, Troupe, & Delinsky, 2012) compared the effect of body exposure therapy in front of the mirror with a non-directive therapy, which dealt with issues related to the development and maintenance of body image alterations in a group of patients with eating disorders. The effect sizes corresponding to the different measures of that study were distributed in a range between 0.4 and 1.6. Consequently, it is decided to calculate the sample size of our study for an effect size of 0.5, so, using a t-test for dependent samples, to a queue (a=0.05, ß = 0.20), a minimum of 27 participants will be required in each of the two study groups, resulting in a total of N=54. It is expected that the sample will be constructed as patients are recruited, replacing dropouts with new cases until the sample size is reached.

3. Measures

3.1. Pre-post treatment measures (both groups) and follow-up after 6 months

Before starting the treatment (pre-evaluation), at the end of the treatment (post-evaluation) and after a follow-up of six months, the participants will be weighed and measured in order to obtain their BMI and they will be administered a battery of tests. In addition, attentional bias towards the body will be assessed using an eye-tracker.

- Evaluation of change in body weight: BMI
- Evaluation of AN symptomatology: Eating Disorders Inventory-3 (EDI-3; Garner, 2004) drive for thinness (EDI-DT) and body dissatisfaction (EDI-BD) scales.
- Evaluation of body image disturbance and body anxiety:
    - Silhouette Test for Adolescents (TSA; Cruz and Maganto, 2003).
    - Physical Appearance State Anxiety Scale (PASTAS; Reed, Thompson, Brannick and Sacco, 1991).
    - Body Appreciation Scale (BAS; Avalos, Tylka and Wood-Barcalow, 2005) translated by (Lobera and Ríos, 2011).
    - Figural Drawing Scale for Body Image Assessment (BIAS-BD), Body dissatisfaction (BIAS-O) and Body distortion (BIAS-X)
- Evaluation of attentional bias towards the body:
    - Complete time of fixation (evaluated in milliseconds) of the gaze towards weight-related and non-weight-related body parts.

- Number of fixations of the gaze towards weight-related and non-weight-related body parts.

3.1. Intra-session measures (experimental group only)

The main objective of the exposure sessions is to achieve the habituation or extinction of the anxiety response to one's own body image and, consequently, the reduction of the fear of gaining weight. In order to control the development of these responses throughout the exposure, subjective anxiety with respect to the body (every 30 seconds) and the fear of gaining weight will be assessed at the beginning and end of each session. The intensity of the body ownership illusion will also be evaluated at the beginning of the exposure. The evaluation will be carried out using analogue visual scales:

- Body-related anxiety (visual analogue scale from 0 to 100)
- Fear of gaining weight (visual analogue scale from 0 to 100)
- Body ownership illusion (visual analogue scale from 0 to 100)

3.2. Interventions

Prior to treatment, written informed consent must be obtained from both the patient's parents or legal guardians and the patient (Appendix 1-3). In addition, the clinicians responsible for each patient will be contacted to check whether or not they meet the inclusion and exclusion criteria and to complete the identification form for the study (Appendix 4).

- **Treatment as usual.** Patients assigned to this group will receive the usual treatment from the centre in which they are recruited for the study (CBT), and will have to complete the evaluations following the same schedule as the experimental group.
- **Experimental treatment.** Patients assigned to this group will receive the usual treatment from the centre in which they are recruited for the study (CBT) and, additionally, the intervention of body exposure through virtual reality, with a minimum of 5 exposure therapy sessions per patient. In each of these sessions, which will take place on a weekly basis, patients will gradually be exposed to increases in the BMI of their virtual avatar. The first exposure session will begin with an avatar owning the same body silhouette as the participant, and then gradually increase the BMI of its virtual avatar to reach a healthy BMI taking into account its age, physique and BMI prior to the onset of the disorder. To move from one level of the exposure hierarchy to the next, it will be necessary to have reduced the initial level of anxiety by 40% with respect to the whole body. Therefore, the patient will be asked about the level of anxiety experienced every 120 seconds throughout the exposure session (visual analogue scale from 0 to 100). To enhance the effect of the intervention, at the beginning of each session a procedure to elicit the illusion of ownership of the virtual body will be applied.

3.3. VR exposure treatment procedure

The VR exposure intervention consists of 6 sessions. In the first one, the pre-evaluation will be carried out and, throughout the remaining 5, the treatment of body exposure through virtual reality. At the end of the last session, the post-evaluation will be carried out. This post-evaluation will be repeated 6 months after the end of the treatment.

The administration of the treatment will be carried out by a general health psychologist with clinical experience in the treatment of adolescents. In addition, during the sessions he will be accompanied by a co-therapist who will be in charge of the induction of the body ownership illusion.

3.3.1. Pre-evaluation session (experimental and control groups, 1h approximately)

<u>Generation of the virtual avatar and administration of the questionnaires (20-30 minutes).</u>

The first 5 minutes of the session will be devoted to explaining to the participant the tasks to be carried out and an identification number will be assigned in order to assure the confidentiality of the data collected throughout the intervention.

Then, to generate the virtual avatar, a frontal and lateral photo of the participant will be taken. In order to take this photograph, the patient's body shape must be easily visible. If the patient wears wider clothes, the clothes will be fixated with tweezers to better mark the body silhouette.

One of the therapists generates the avatar's silhouette from the photographs taken. To do this, he will adjust the different parts of the avatar's silhouette (shoulders, arms, chest, waist, stomach, hip, thighs and legs) to the photograph, so that the virtual avatar has the same silhouette as the patient. In the meantime, the other therapist

will administer the pre-evaluation questionnaires and answer any questions the patient may have. Once the questionnaires have been completed, there will be a short pause (5 min maximum), so that they can drink water and rest if they want to.

Visomotor and viso-tactile stimulation procedures with Virtual Reality (from 15 to 20 min).
Next, the ownership illusion of the virtual body (avatar) will be induced. Two different procedures (visuo-motor stimulation and visuo-tactile stimulation) and the HTC-VIVE virtual reality glasses will be used.
Visuo-motor stimulation procedure: consists of synchronizing the participant's movement with the avatar's movement through the use of motion capture sensors placed on hands, feet and waist. Once inside the virtual environment, the patient will be able to observe himself or herself in the first person perspective and/or to look at himself or herself in a mirror (3rd person). The movements will be carried out in a structured way and will be the same for all participants. This procedure will have a total duration of one and a half minutes.
Visuo-tactile stimulation procedure: this consists of synchronising the participant's visual and tactile stimulation. While the participant is touched with one of the HTC-VIVE controller in different areas of the body (upper extremities, lower extremities and stomach) for one and a half minutes, they will see (in first and third person) how their avatar is being touched in the same areas and at the same time by a virtual controller. The visuo-tactile stimulation will be performed by a person of the same gender as the participant.
Once the illusion of ownership of the virtual body is induced, the three visual analogue scales (VAS) will be administered in which body-related anxiety, fear of gaining weight and the intensity of the ownership illusion are evaluated from 0 to 10 (Annex 5). Then, the HTC-VIVE glasses will be removed, to start the registration with Eye-tracker.

Evaluation of attentional bias towards the body using Eye-tracking and Virtual Reality (5 - 10 min).
The participant is put on FOVE VR virtual reality glasses, with an incorporated eye-tracker. To mask the objective of the test, it is explained that the position of their virtual body will be recalibrated with other virtual reality glasses. They are also told that during this process they must remain completely still, but that they can observe their virtual body in the mirror in front of them. After calibrating the eye-tracker (30 seconds), the registration of eye movements begins. For 30 seconds, the participant will be asked to observe their virtual body in the mirror. Once the assessment is finished, the FOVE glasses are removed and the first evaluation session is finished.

3.3.2. Exposure sessions to the body by VR (experimental group). Approximate duration: 45 minutes to 1 hour per session
Each exposure session will begin by inducing the body ownership illusion using the procedures mentioned above. Once the visuo-motor and visuo-tactile stimulation has been completed, the level of anxiety regarding the entire body, the fear of gaining weight and the intensity of the ownership illusion will be evaluated using VASs from 0 to 100. The body exposure treatment will be initiated with a virtual body or avatar with the same BMI of the participant. During the following sessions, the BMI of the avatar will be progressively increased until the target weight (healthy BMI) is reached.
Once the participant has been exposed to all parts of the body, they will be asked about their anxiety towards the whole body and their fear of gaining weight again. When the anxiety has decreased by 40% compared to the initial anxiety, the session will be terminated (if the remaining session time is no more than 15 minutes) or it will be continued with the next level of the hierarchy (avatar with slightly higher BMI) and the whole process will be repeated.
At the end of each session, the patient will be exposed to a relaxing VR environment (forest or garden) and 5 to 10 minutes will be devoted to addressing any concerns, emotions or negative thoughts that may have arisen during the session, with the aim of reducing the participant´s experienced anxiety level to a minimum.
Each treatment session will begin with the next item in the hierarchy (or BMI increase). In cases where the initial whole-body anxiety has not been reduced by 40% or exposure to different parts of the body has not been completed, exposure to the same avatar from the previous session will be repeated. Finally, in those cases where the initial anxiety is equal to or less than 30 (on a scale from 0 to 100), it will be continued with the next part of the body or the next avatar in the hierarchy.
Note: Patients will not be informed about the increase in BMI of the virtual body in each of the exposure sessions, but they can be informed about how many items in the hierarchy they still have to complete.