Application of the unified protocol for transdiagnostic treatment of emotional disorders in post-bariatric surgery patients: an effectiveness and feasibility study in group format

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Abstract: Obesity is a serious health problem with global implications. Bariatric surgery (BS) is the most used and effective treatment, but there are patients who do not lose a substantial amount of weight, a fact that has been related with the presence of emotional eating, anxiety and depression symptoms. The aim of this study is to analyze the effectiveness and feasibility of an emotion regulation-based intervention called Unified Protocol (UP), applied in group format to 6 post-BS patients presenting emotional disorders/symptoms. Results at post-treatment showed high attendance rates and satisfaction with the UP scores and significant improvements on neuroticism, eating disorders symptoms and emotional eating. At 6-month follow-up we found significant reductions on anxiety symptoms, neuroticism, maladjustment and dysregulation (d = 0.83-1.46) and the body mass index remained stable over time. These preliminary results are encouraging about the effectiveness and feasibility of the UP to treat emotional dysregulation in patients after BS.


Introduction

Obesity is currently becoming a serious health problem with global economic and social implications (Spiriou et al., 2020). In 34 of the 36 member countries of the Organization for Economic Co-operation and Development (OECD), one in four people suffer obesity, and it is expected that in 2050, there will be around 92 million premature deaths from obesity-related diseases in these countries (OECD, 2019). In Spain alone, it is expected that, by the year 2030, more than 27.2 million people will present with overweight or obesity (Hernández et al., 2019).

Obesity is related to different physical health problems such as myocardial infarction, hypertension, diabetes mellitus, or obstructive sleep apnea (Castañeda et al., 2019), and also with mental health problems, as it is associated with an increase of approximately 25% in the probability of developing mood and anxiety disorders (Simon et al., 2006). These associations have implications for the quality of life and functioning of people with obesity (Spiriou et al., 2020), and they imply high costs for the health systems of the different countries, approximately 8.4% of the total cost in medical attention (OECD, 2019).

For all these reasons, research has increased to seek effective treatments for weight loss in patients with obesity. The three general treatment approaches for obesity are behavioral, pharmacological and surgical (Bean et al., 2008). To date, bariatric surgery (BS), which includes a group of surgical procedures performed to facilitate weight loss, such as open or laparoscopic roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding (Jumbe et al., 2017), is the most used and effective treatment in these cases (Laurien et al., 2020). Despite being the most effective method currently, between 20% to 50% of operated patients begin to regain their weight within the first 1.5 to 2 years following surgery (Cassin et al., 2013), and it seems that the factors that have been most strongly associated with these outcomes are emotional eating, anxiety, and depression (Helmesaeth et al., 2019).

Due to the multidisciplinary and complex nature of obesity and related problems, the role that mental health providers can play in identifying and intervening on these types of problems is essential (Wilfley et al., 2010). In the specific case of the BS, psychological interventions can make a significant contribution to the management of post-BS patients, enhancing compliance and maximizing weight loss, psycho-social functioning, and quality of life after surgery (Kalarchi-
an & Marcus, 2003). A recent systematic review shows that Cognitive Behavioral Therapy (CBT) has accumulated the most evidence to date for the treatment of specific psychological symptoms in these patients (Spirou et al., 2020), and it seems that the optimal time to apply this type of intervention is between the first and the second year after BS, when weight loss tends to stagnate and emotional aspects often appear (Hjelmestad et al., 2019).

Considering that emotional eating, anxiety, and depression are symptoms that appear to be associated with poor weight loss, it would be interesting to see what these symptoms have in common and find an intervention that can address all of them at the same time. In this sense, the transdiagnostic treatments aim to address various disorders at the same time, based on the identification of the etiological and maintenance mechanisms they share (Sauer-Zavala et al., 2017). Within this model, Brown and Barlow (2009) focused their study on emotional disorders (EDs), which encompass unipolar mood disorders, anxiety disorders, and related disorders (emotional eating could also be included in this category). These authors proposed neuroticism as a central dimension in the etiology, course, and maintenance of EDs. This personality dimension is responsible for: a) the frequent experience of strong emotions (e.g., anxiety, sadness, guilt), b) the negative reaction to these emotions (e.g., “I shouldn’t be feeling this way”), and c) efforts to avoid them. David H. Barlow and his team developed the Unified Protocol (UP) for the Transdiagnostic Treatment of Emotional Disorders for the treatment of neuroticism (Barlow et al., 2018).

Neuroticism has special relevance for public health due to its high correlation with different physical and mental health problems, and with the high frequency of the use of general and mental health services (Lahey, 2009), so addressing this trait can have numerous advantages for health services. Furthermore, it has also been associated with worse BS results (Oltmanns et al., 2020), so reducing it may improve BS outcomes.

The UP is an emotion regulation-based CBT intervention that consists of 8 modules, five of which are considered central: mindful emotion awareness, cognitive flexibility, countering emotional behaviors, confronting physical sensations, and emotion exposure. Its objective is to equip patients with emotion-regulation strategies so that they can tolerate intense emotions without giving up their personal goals (Barlow et al., 2018). Although the UP is a structured intervention, it stands out for its flexibility and versatility, which allows it to be easily adapted and administered to a wide range of different problems (Sauer-Zavala et al., 2019). For example, the duration of any of its modules can be increased or their order changed to adapt them to each sample and concrete context (Sauer-Zavala et al., 2019). In this sense, one of the main potentials of the UP in public health systems is the possibility of applying it in group format. This format is advantageous both for the health system and the participants because, on the one hand, it allows caring for several patients at the same time, reducing waiting lists and consultation time; on the other, it facilitates social support through the group participants, allowing them to share their experiences and learn from each other (Yalom & Leszcz, 2005).

To date, the UP has shown strong empirical support, significantly improving emotional symptoms after the intervention, obtaining effect sizes that are at least comparable to the specific existing CBT protocols (Barlow et al., 2017). Moreover, it has shown greater efficacy in the treatment of neuroticism, with significantly lower scores for this variable compared to specific CBT protocols (Sauer-Zavala et al., 2020). This support has been obtained for the treatment of distinct EDs when applying UP in different formats (individual and group, online and in-person) and also when comorbid health conditions, such as HIV, cancer, or irritable bowel syndrome, are present (Cassiello-Robbins et al., 2020). Indeed, data from a systematic review explicitly explore preliminary data about the effectiveness and feasibility of UP for treating EDs in people with other comorbid medical conditions (Osma et al., 2021). On a prevention level, UP has recently been applied in Spain in a group of women with fertility problems (Martínez-Borba et al., 2022).

Therefore, the general objective of this study is to verify the preliminary effectiveness and feasibility (acceptance, satisfaction, adherence) of the UP applied in group format in a mental health unit of the Spanish public health system to post-BS patients who present a diagnosis of ED or anxious or depressive symptoms. Specific objectives are: 1) to obtain data that confirm participants’ acceptance of the intervention through high rates of session attendance and high scores in satisfaction with treatment; 2) to obtain a statistically significant reduction in the scores of depression, anxiety, neuroticism, maladjustment, emotional dysregulation, dysfunctional eating behaviors, dissatisfaction with body image, emotional eating, and body mass index; 3) to obtain a statistically significant increase in the scores of extraversion and quality of life; and 4) to confirm that the changes achieved after the intervention are maintained at a 6-month follow-up.

Method

Participants

Nine participants were referred to the study, two of whom were discarded for not meeting the inclusion criteria and one could not start the group due to schedule incompatibility. The total sample of this study consisted of 6 participants, all of them Spanish women, with a mean age of 49.57 years ($SD = 7.74; range = 35-57$). At the time of the start of the intervention, 5 of them had undergone BS 13.80 months ago on average ($SD = 7.53; range = 6-21$), and the other participant was operated on between UP Sessions 1 and 2. The rest of the sociodemographic and clinical characteristics of the participants are shown in the “Detailed description of the cases” section.

The following inclusion criteria in the study were followed: (1) being over 18 years of age; (2) being a BS candi-
date or being a post-BS patient (for more information see the inclusion criteria and the main contraindications that are evaluated for BS in the Spanish Health System in Martín et al., (2017), a guide written in collaboration with different obesity surgery associations); (3) presenting anxious or depressive symptomatology: moderate scores on the Beck Depression Inventory-II (Beck et al., 1996) and/or Beck Anxiety Inventory (Beck & Steer, 1993) or meeting the criteria for at least one ED on the International Neuropsychiatric Interview (Sheehan, 2015); (4) speaking Spanish or Catalan fluently, (5) committing to attend the sessions, and (6) understanding and accepting the contents of the informed consent, expressed by signing it. In addition, the following exclusion was included: (1) having a severe condition that would require being prioritized for treatment, so that an interaction between the two interventions could not be ruled out. These included a severe mental disorder (bipolar disorder, personality disorder, schizophrenia, or an organic mental disorder), suicide risk at the time of assessment, or substance use in the previous three months (excluding cannabis, coffee, and/or nicotine).

**Detailed description of the cases**

**Participant 1**

She is a single 35-year-old, with no children and a professional training qualification. She is currently working in her own hospitality business. She underwent BS in January 2018 (21 months before starting this intervention), and currently, she has a diagnosis of depressive disorder reactive to the intervention.

This participant went to the mental health unit for the first time in October 2018 (9 months after the surgery). No significant psychopathological history appeared and the results of the BS were satisfactory. The reason for consultation was: constant feelings of tiredness, decreased illusions, discouragement, and internal nervousness. The patient had been under the care of a psychiatrist until December 2018, when she was referred to a psychologist because she still presented with emotional symptoms reactive to the vital change that BS has produced. In May 2019, she undertook life changes on her own initiative, but she did not feel as good as she would like, and she had many doubts about the decisions she had made. It was at this time that she started the group therapy described in this study.

**Participant 2**

She is a married 56-year-old, with one child and a professional training qualification. Currently, she is unemployed. She underwent BS in April 2019 (6 months before the start of this intervention), with satisfactory results. Currently, she has a diagnosis of adjustment disorder but not directly related to the BS process.

There is no psychopathological history. She was referred to the mental health unit by the family doctor in October 2019 and the clinician considered her as a candidate for the proposed group treatment. The participant presented with hyperphagia (excessive increase in appetite sensation and uncontrolled food intake). She felt anxious, with an irritable mood and she had conciliation and maintenance insomnia. The main request was that the current situation and anxiety levels (that she attributed to the bad relationship with her daughter-in-law) should not affect the good results of the BS due to her worsening eating habits. The participant said that all she wanted was to manage her symptoms to maintain the results of the BS, so she was referred to the intervention described in this study.

**Participant 3**

She is a single 47-year-old, with no children and a professional training qualification. Currently, she is working actively. She was the only participant who joined the group without having undergone BS to continue working on her eating habits and learn about the experiences of people who had already had the operation. She underwent BS in November 2019, after the first UP treatment session, and the results of BS were satisfactory. She currently has a diagnosis of depressive disorder and an unspecified eating disorder.

The first time she attended the mental health unit was in August 2013, although she did not continue attending the sessions. In February 2014, she returned, referred by the endocrinologist for compulsive intake, and she had gained 54 kilos. They began to work on the symptoms of a binge-eating disorder, managing food through different techniques. Little by little, she began losing weight and her eating habits were improving. In February 2018, she received a positive psychiatric evaluation for BS but she had to continue with strict controls in the mental health unit. She continued like this for several months until September 2019, by which time she had lost 16 kilos and began the group intervention developed in this study.

**Participant 4**

She is a single 57-year-old, with no children and a professional training qualification. She works in her own beauty business. She underwent BS in January 2018 (21 months before the therapeutic group began), and the results of BS were satisfactory. Currently, she has a diagnosis of depressive disorder in remission.

She had not previously visited the mental health unit, but she had visited different private psychiatrists. This participant had presented with obesity throughout her life, with different depressive symptoms that the family doctor and private psychiatrists had treated with medication. She had dysfunctional obsessive personality traits, high levels of impulsiveness, and high emotional reactivity. At the time of the BS, she was psychically stable, but she developed a post-BS
depressive disorder, for which she was referred to the mental health unit to begin the present group intervention.

Participant 5

She is a married 55-year-old, with three children and a basic level of education and she is a homemaker. She underwent BS in July 2018 (15 months before the start of this intervention), with satisfactory results. Currently, she has a diagnosis of dysthymia and a secondary diagnosis of unspecified eating disorder.

She was referred to the mental health unit for the first time in June 2014. At that time, she was diagnosed with dysthymia, and she started a pharmacological treatment recommended by the psychiatrist. The specialist reported improvements in mood thanks to the treatment, but also binge episodes that decreased but never disappeared. In January 2016, she was proposed as a candidate for BS but she did not pass the psychiatric evaluation, so she was referred to the psychology unit to work on the intake pattern and to be re-evaluated for BS in the future. In December 2017, the participant continued to present lack of intake control, with continued eating and a permanent feeling of hunger. These variables were addressed by the clinician through different techniques and she began to improve and to lose weight. She was declared BS fit in April 2018, but dysthymia and some maladaptive eating patterns were maintained, so she began the group treatment described in the present study.

Participant 6

She is a 51-year-old with a professional training qualification who lives with her partner and their three children and is currently working actively. She underwent BS in April 2018 (6 months before the start of this intervention), and BS results were satisfactory. Currently, she has a diagnosis of adjustment disorder reactive to BS.

She had no psychopathological history and she had not been treated in the mental health unit before. The endocrinologist referred her, believing that she probably had mood problems. She had emotional symptoms that she described as unexpected anxiety attacks and low mood that were not related to any trigger. She had a stable family, social, personal, and work life. She attributed her symptomatology to the changes associated with BS.

Instruments

The MINI-International Neuropsychiatric Interview: structured diagnostic psychiatric interview for DSM-IV and ICD-10 (MINI; Sheehan et al., 1998; Spanish validation by Ferrando et al., 2000). It is an interview that evaluates the main psychiatric disorders based on the diagnostic criteria of the DSM-IV (American Psychiatric Association, 1994) and ICD-10 (World Health Organization, 1992). It is divided into 16 modules, each of which has structured questions that refer to the different diagnostic categories. It shows a value of .75 for Cohen’s kappa, which shows the inter-judge reliability (Sheehan et al., 1998).

Beck Depression Inventory (BDI-II; Beck et al., 1996; Spanish validation by Sanz et al., 2003). It is an instrument that assesses symptoms of depression through 21 items that are answered on a 4-point Likert-type scale between 0 (Not at all) and 3 (Severely, I can hardly bear it). The total score ranges from 0 to 63, and higher scores indicate a higher level of depressive symptoms. In the Spanish validation study with a clinical sample, a score of .89 was obtained for Cronbach’s alpha (Sanz et al., 2005).

Beck Anxiety Inventory (BAI; Beck & Steer, 1993; Spanish validation by Magán et al., 2008). It is a questionnaire that assesses anxiety symptoms through 21 items that are answered on a 4-point Likert scale, between 0 (Not at all) and 3 (Severely). The total score ranges from 0 to 63, and higher scores indicate a higher level of anxiety symptoms. In the Spanish validation study with a clinical sample, .91 was obtained as Cronbach’s alpha (Sanz et al., 2012).

Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2013; Spanish validation by Osma et al., 2019). It is a short scale that assesses the frequency, intensity, and interference of anxiety symptoms. It is made up of 5 items that are answered on a 5-point Likert-type scale, between 0 (I did not feel anxious at all) and 4 (Constant anxiety). The total score ranges from 0 to 20, and higher scores indicate greater severity and interference with anxiety symptoms. In the Spanish validation study with clinical sample, .87 was obtained as Cronbach’s Alpha (Osma et al., 2019).

Overall Depression Severity and Impairment Scale (ODSIV; Bentley et al., 2014; Spanish validation by Osma et al., 2019). It is a short questionnaire that assesses the frequency, intensity and interference of depressive symptoms. It is made up of 5 items that are answered on a 5-point Likert-type scale, which ranges from 0 (I did not feel depressed at all) to 4 (Constant depression). The total score can range from 0 to 20, and higher scores indicate greater severity and interference with depressive symptoms. In the Spanish validation study with a clinical sample, a Cronbach’s alpha score of .96 was obtained (Osma et al., 2019).

NEO-FFI Personality Inventory (NEO-FFI; Costa & McCrae, 1999). It is a scale that assesses the Big Five personality factors in a general way. In the present study, only the Neuroticism and Extraversion subscales have been administered and taken into account. Each subscale is made up of 12 items that are answered on a Likert-type scale from 0 (Totally agree) to 4 (Totally disagree). The total score for each subscale is calculated by adding the items of said subscale, and the higher the score, the greater the presence of the personality trait evaluated. In the Spanish validation study, Cronbach’s alpha scores obtained for the different subscales ranged between .82 and .90 (Costa & McCrae, 1999).

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004; Spanish validation by Hervás & Jodar, 2008). It is a scale that evaluates five dimensions of emotional
dysregulation: emotional lack of control, emotional rejection, interference from emotions, emotional inattention and emotional confusion. It is made up of 28 items that are answered through a 5-point Likert-type scale, which ranges from 1 (Almost never / 0-10% of the time) to 5 (Almost always / 90-100% of the time). The total score is the sum of the score of the items of each subscale, and the higher the score, the greater the emotional dysregulation. The Cronbach's alpha scores obtained in the Spanish validation study for the different subscales ranged between .73 and .91 (Hervás & Jódar, 2008).

**Quality of Life Index (QLI; Mezzich et al., 2000).** It is a questionnaire that assesses quality of life through different dimensions of daily life: physical well-being, emotional or psychological well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social-emotional support, community and service support, personal fulfillment, spiritual fulfillment and global perception of quality of life. The questionnaire is made up of 10 items that are evaluated on a 10-point Likert-type scale ranging from 1 (Bad) to 10 (Excellent). The total score is an average of the item scores, and the higher the score, the higher the quality of life. In the Spanish validation study, a Cronbach's alpha of .89 was obtained (Mezzich et al., 2000).

**Maladjustment Inventory (MI; Echeburúa et al., 2000).** It is a scale that assesses the extent to which the person's current problems affect different areas of their life: work or studies, social life, free time, relationship with a partner, family life, and day-to-day maladjustment. It is made up of 6 items, one for each dimension, which are answered using a Likert-type scale that ranges from 0 (Not at all) to 6 (Very serious). The total score ranges from 0 to 30 and the higher the scores, the more interference from problems in everyday life. In the validation study with the Spanish sample, a Cronbach's alpha of .94 was obtained (Echeburúa et al., 2000).

**Bulimic Investigatory Test (BITE; Henderson & Freeman, 1987; Spanish validation by Moya et al., 2004).** It is a questionnaire that assesses the presence and severity of bulimia symptoms, taking into account cognitive and emotional signs and symptoms associated with bingeing. It is made up of 33 items that are answered on a dichotomous scale (Yes / No). The total score ranges from 0 to 69, and a score from 15 indicates that you have many thoughts and attitudes consistent with an eating disorder. Cronbach's alpha obtained in the validation study in Spanish is .81 (Moya et al., 2004).

**Emotional Eating Scale (EES; Arnow et al., 1995; Spanish validation by Perpiñá, et al., 2011).** It is a scale that evaluates the tendency to eat driven by different emotions. It is made up of 25 items, and each of them explores the tendency to eat when faced with a different unpleasant emotion, with a 5-point Likert-type scale that ranges from 0 (No desire to eat) to 4 (An irresistible urge to eat). The internal consistency obtained in the validation study into Spanish ranges between .60 and .75 (Perpiñá et al., 2011).

**Body Shape Questionnaire (BSQ; Cooper et al., 1987; Spanish validation by Raich et al., 1996).** It is a questionnaire that assesses dissatisfaction with body image, through the exploration of fear of gaining weight, low self-esteem and the desire to lose weight. It is made up of 34 items that are answered on a 6-point Likert-type scale, ranging from 1 (Never) to 6 (Always). In the validation into Spanish, 105 is indicated as a cut-off point, although in the development of the original scale different ranges are established: scores lower than 81, no concern for body image; between 81 and 110 mild concern about body image; between 111 and 140 moderate concern for body image; above 140, extreme concern for body image. The Cronbach's alpha value obtained in the validation into Spanish was .97 (Raich et al., 1996).

**Satisfaction with Treatment Questionnaire (STQ; an adaptation of Client Satisfaction Questionnaire [CSQ-8] of Larsen et al., 1979).** The CSQ-8 is made up of 8 items that evaluate customer satisfaction with the service they have received. Our adaptation includes 6 of the 8 items of the CSQ-8 (perceived quality, suitability to the previous expectations, recommendation of treatment to friends or family, the usefulness of the techniques learned, general satisfaction with the intervention, and the probability that they will choose an intervention of this type again) and one more item regarding the discomfort that the intervention has generated. All 7 items are answered by means of a Likert-type scale that ranges from 0 (Bad / Not at all) to 4 (Excellent / Very much). The higher the total score, the greater the satisfaction with the treatment program received. The CSQ-8 have shown Cronbach's alpha ranged between .86 and .94.

**Procedure**

The study was carried out at the mental health unit of the Hospital Comarcal of Vinaròs within the Spanish public health system. We used a convenience sampling method to conduct this effectiveness and feasibility study.

The participants were informed of the existence of the study by the different specialists that form the multidisciplinary team of care for patients who received the BS, through the information document. Participation was voluntary and without financial reward. If they wanted to participate in the study, they were referred to the clinician of the mental health unit, who gave them the informed consent document and, after they signed it, evaluated them to verify that they met the selection criteria (see “Participants” section). The clinician administered the evaluation battery in pencil and paper format to the participants (all the information was collected using alphanumeric codes to preserve the participants' identity).

Once the pre-treatment evaluation battery was completed, the intervention was carried out (see “Intervention” section). The sessions were carried out by a clinician (V.F.G.) and a co-therapist (A.Q.O). The clinician was the one who developed most of the session, explaining the theoretical content and resolving the doubts of the participants. The co-therapist, who was a doctoral student, was an observer and she intervened to complement the work of the clinician and
to help participants with their in-session exercises. To ensure the proper implementation of the UP, the clinician received a UP training course and clinical supervision by the leading author (J.O.) who has been certified as a UP trainer by the Unified Protocol Institute and had extensive experience in applying the UP. The clinician has extensive experience in the application of cognitive behavioral treatments (14 years of professional practice) and also has completed the UP therapist training. The role of the supervisor was crucial throughout the implementation of the intervention program, since meetings were held prior to each session to analyze how the previous session had gone and to resolve possible doubts or conflicts and are also helpful to prepare the following session. To monitor and improve the training of the participants, throughout the sessions they received different theoretical documentation that summarized the contents of the next session, for example, specific information about emotional eating or a summary of the UP modules from the participants’ manual (Barlow et al., 2019). The idea was that the participants read these documents before the following session, to better understand the contents and have time to review them. In addition, at the end of each session the exercises and their own records were delivered, in paper format, so that they could fill them in as homework until the following session, in which they were shared and corrected.

The assessment protocol was administered at pre-treatment, post-treatment, and 6-month follow-up. As previously mentioned, the evaluation batteries at the pre-treatment and post-treatment time were carried out by the participants in pencil and paper format in the mental health unit itself and in the presence of their clinician, who answered questions and supervised the completion of the questionnaires. However, the evaluation batteries of the follow-up at 3 and 6 months were filled out by means of a survey on the Qualtrics platform (Qualtrics, 2017), so that the participants did not have to travel to their mental health unit.

**Intervention**

The UP adaptation for the present study consisted of 9 two-hour group sessions, with a weekly frequency, in which 6 of the 8 modules of the original UP (Barlow et al., 2015) were applied. The main adaptation was to grant special relevance to emotional eating and the relationship between food and emotions. Table 1 shows the original UP modules, the number of sessions dedicated to each of them, and the main adaptations for this sample.

<table>
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<tr>
<th>Modules of the original UP (number of sessions in adaptation)</th>
<th>Adaptations of each module</th>
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<tr>
<td>Setting goals and maintaining motivation (0)</td>
<td>Given the high motivation for change of the majority of participants, and the existence of a common objective, which was to regulate their eating habits so as not to channel with food and maintain weight, this module was replaced by one specifically designed to introduce psychoeducation on emotional eating, and also on the relationship between food and emotions. In addition, the participants were told what the intervention would consist of and the logic behind the skills that would be worked on in relation to the main problem was explained. The importance of participating in sessions, group norms and the important role of doing the homework were also highlighted.</td>
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<td>Understanding emotions: psychoeducation and recording of emotional experiences (1)</td>
<td>The module’s content was applied on the basis of the experiences of the participants that could be related directly or indirectly to food. In this module, the focus was on contextualizing binging or snacking as an emotion-driven behavior, introducing this concept from this session. Part of the session was also used to detect the association between different emotions and binge or pecking episodes, so that each participant established their own association pattern. The importance that positive emotions can also be associated with binge episodes was highlighted.</td>
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<tr>
<td>Mindfulness: Training in emotional awareness and experimentation of the present moment (1)</td>
<td>This module was applied following the same guidelines as the original UP, although specific exercises were carried out that focused mindfulness exercises on food-related activities.</td>
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<tr>
<td>Cognitive flexibility: Cognitive reinterpretation and Identification of thought patterns (2)</td>
<td>Two sessions were dedicated to this module, because the participants manifested difficulties in understanding its content. The exercises were adapted to the specific experiences that the participants presented in the session. Some of the most characteristic irrational automatic thoughts were: &quot;I need to eat to reduce my sorrows&quot;, &quot;even though I don’t weigh much anymore, I’m still fat&quot;.</td>
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<tr>
<td>Opposing Emotional Behaviors: Emotional Avoidance and Emotion Driven/Directed Behaviors (1)</td>
<td>This module was applied following the same guidelines as the original UP, although the emotion-driven behaviors that the participants reported were closely related to emotional eating, so special attention was paid to this topic. Some examples of specific emotional behaviors the participants exhibited were &quot;wearing wide, dark clothes&quot;, &quot;not going to the pool&quot;, or &quot;not going through certain areas of the supermarket&quot;.</td>
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Data analysis

The analyses were carried out using the statistical package IBM SPSS Statistics version 22.0 for Windows (IBM Corp., 2013). First, the sociodemographic characteristics of the total sample (N = 6) were analyzed using descriptive statistics. The mean and standard deviation of the scores in the different questionnaires were calculated. Then, a Missing Values Analysis and Little’s MCAR were carried out to test whether or not the distribution of these missing values was random. Once its random distribution was verified, the LOCF (Last Observation Carried Forward) was used for those cases in which some random item from a scale was missing. The Shapiro-Wilk normality test was carried out to verify the normal distribution of the variables.

A record of attendance at the sessions was carried out to calculate attendance and dropout rates, and to use them as an indicator of feasibility and acceptance of treatment by users. For this same purpose, both quantitative and qualitative analyses were performed. At the quantitative level, descriptive analyses were performed to assess responses to the Satisfaction Treatment Questionnaire (STQ). At a qualitative level, the answers to the four main treatment questions were analyzed, selecting and ordering the information through a segmentation process, identification of key concepts and categories of analysis (De Andrés Pizarro, 2000).

To explore the effectiveness of this intervention, changes in participants’ symptoms were analyzed throughout the different time points. For this purpose, and although the scores followed a normal distribution, we decided to carry out non-parametric tests because the sample did not meet the rest of the parametric assumptions. Therefore, the Wilcoxon-Singed Rank test was conducted to calculate the differences between mean ranks when comparing pre- and post-treatment, and post-treatment and 6-month follow-up. Effect size was calculated with Cohen’s d, and interpretation of effect sizes was as follows: 0.2 represented a small clinical treatment effect, 0.5 a medium effect and 0.8 or above a large effect (Cohen, 1960). Also, the Friedman test was conducted to assess the change in the scores of the different variables, taking into account the variation at different time points.

Finally, we calculated the Reliable Change Index (RCI), which is defined as a statistical index that evaluates the clinically significant change obtained to determine in which variables each of the participants approaches the scores of a normative sample. A clinically significant change would be considered if the participant obtained scores in the variables that reflect normal functioning, which would imply a score in the RCI of 1.96 or higher (Jacobson & Truax, 1991).

Results

Descriptive analysis

The results of the descriptive analysis of the characteristics of the sample are found in the “Participants” section. The mean scores for each of the instruments are shown in Table 2. The Missing Values Analysis shows that out of the total set of all variables, 8.75% of the data was lost. In Little’s MCAR-test, a significance of α = 1.00 (p > .05) was obtained, which implies a random distribution of missing values. Based on this, the LOCF was conducted for such missing values. The results of the Shapiro-Wilk normality test showed that the scores of the participants in the different variables were normally distributed (p > .05), but the rest of the parametric assumptions were not met.

Feasibility and satisfaction with the intervention

The participants attended a general average of 8 sessions (SD = 0.82; range = 7-9), representing an attendance rate of 88.89%. In the STQ, 83.3% of the participants rated the quality of the program as good, and 66.7% reported high satisfaction and stated that they would recommend it to a loved one. The same percentage deemed that the contents of the program helped them to deal with their problems and said that they would choose a similar treatment again.

Finally, to analyze the participants’ qualitative assessments, their responses to the four questions that were asked at the end of the treatment were coded. To the question "What did you not like, what did you find difficult or what caused you discomfort?" three participants answered "nothing," two mentioned "difficulty understanding and putting into practice some concepts," and one participant commented, "I still cannot control the urge to eat very well." To the question "Do you recognize any obstacle for this type of treatment to continue being applied in the public health system?" all the participants replied negatively with words like "not at all" or "just the opposite." To the question "What positive aspects would you highlight and
what did you like or what interested you the most?" four participants made reference to the social support, with phrases such as "meeting people in the same situation" and "being able to share my experiences." One participant mentioned "interest on the part of the therapists" and another made reference to the improvement in emotion-regulation skills "getting to know myself better, managing my emotions better and not judging". Finally, to the question "What ideas can you think of to improve the intervention?" two participants answered "none", two participants mentioned the need for "more nutritional or physical activity information" related to BS, one participant said expanding the number of sessions, and another mentioned interspersing group sessions with individual sessions.

**Effectiveness at group level**

Table 2 shows the results of the Friedman and Wilcoxon tests (and Cohen's $d$). Pre- to post-treatment comparisons showed statistically significant improvements in neuroticism ($Z = -2.21, p = .027$), symptoms related to eating disorders ($Z = -2.00, p = .046$), and emotional eating ($Z = -2.20, p = .028$). Post-treatment to 6-month follow-up comparisons showed statistically significant changes in anxiety symptoms ($Z = -2.02, p = .043$), neuroticism ($Z = -2.00, p = .046$), extraversion ($Z = -2.02, p = .043$), maladjustment ($Z = -2.21, p = .027$), emotional dysregulation ($Z = -2.21, p = .027$), and DERS' rejection subscale ($Z = -2.20, p = .028$); all of them with a medium or large effect size (0.64 < $d$ < 1.46).

Taking into account all the temporal moments, the Friedman test showed that the variables with statistically significant changes were neuroticism ($\chi^2 = 13.56, p = .004$), maladjustment ($\chi^2 = 9.56, p = .023$), emotional dysregulation ($\chi^2 = 10.68, p = .014$), and DERS' confusion ($\chi^2 = 8.41, p = .038$), rejection ($\chi^2 = 11.13, p = .011$) and interference ($\chi^2 = 9.63, p = .022$) subscales.

Thus, the results showed that the main changes occurred in neuroticism and emotional dysregulation (variables directly addressed by the UP), but also in variables directly related to overweight, obesity, and BS. In this sense, although there were only statistically significant changes for the symptoms of eating disorders and emotional eating, there were also reductions in dissatisfaction with body image and BMI (although they were not statistically significant). Finally, the body mass index remained stable over the treatment to 6-month follow-up.

**Effectiveness at the individual level**

Regarding the Reliable Change Index (RCI) analyses (Table 3), the number of participants who normalized their scores at post-treatment on each measure were as follows: 4 for dissatisfaction with body image; 3 for maladjustment and rejection DERS subscale; 2 for emotional dysregulation; 1 for neuroticism, extraversion, quality of life and lack of attention, confusion, interference and lack of control DERS subscales.
The number of participants who normalized their scores from post-treatment to the 6-month follow-up on each measure were: 5 for dissatisfaction with body image; 4 for maladjustment, emotional dysregulation, and rejection DERS subscale; 3 for quality of life, and interference and lack of control DERS subscales; 2 for neuroticism and confusion DERS subscale; and 1 for extraversion and lack of attention DERS subscale.

Discussion
This is the first study to apply the UP, an emotion-based CBT intervention in a group format in a public mental health unit for a sample of post-BS patients with a diagnosis of an ED or anxious depressive symptoms. The preliminary results especially highlight the feasibility and acceptance of this intervention by participants and show preliminary data of its effectiveness for this specific health problem.

The recommendation to conduct an intervention focused on the improvement of emotion-regulation strategies in post-BS patients is based on the presence of emotional symptoms reactive to BS (four participants in our study, 66.67%), and also on that some people in these circumstances have prior psychopathological history (two participants in our study, 33.33%), which has been shown to be a risk factor for poorer or limited BS results, and finally, because of the numerous physical and functional changes produced by BS (e.g., drastic weight loss, body image concerns, mood changes, stress; Jumbe et al., 2017). Carrying out interventions such as the one described in this study, the UP, allows to care for the psychological well-being of post-BS patients, which is one of the main needs of these people to improve their BS results and, thereby, their health (Spirou et al., 2020).

One of the clearest results provided by the present study is the high attendance rate and adherence to the intervention. The attendance rate was very high compared with other studies that have applied other CBT interventions (Cassin et al., 2016; Sockalingam et al., 2017; Sokalingam et al., 2019). The STQ results show high satisfaction with the treatment received, data that generally agree with those obtained in other psychosocial interventions. This shows that post-BS patients generally express high satisfaction with the treatment, and these levels of satisfaction can predict adherence to subsequent follow-up sessions (Lauren et al., 2020).

The qualitative analysis of participants’ opinion of the treatment received has shown some positive aspects. None of the participants detected obstacles to the application of this type of intervention in a public health context, confirming its probable feasibility in a naturalistic context. In addition, one of the most positive aspects that the participants highlight is the perception of social support, something previously found in the literature (Valom & Leszcz, 2005). Through this survey, ideas for future interventions were also detected, such as increasing the information about topics directly related to BS (nutritional information, physical activity, etc.). These ideas are in line with those obtained by Lauren et al. (2020), who recommended incorporating a dietary or physical activity as part of the psychological interventions’ focus on these patients. Participants also recommended increasing the number of sessions or inserting individual sessions throughout the intervention. This aspect would be crucial to be able to address the specific needs of each participant, dedicating more time to those concepts that take longer to understand, or adding techniques that may be necessary for specific cases.

Regarding the effectiveness, the intervention also shows encouraging preliminary results. At the 6-month follow-up, a generalized decrease or a positive tendency in the expected direction was observed in all study outcomes. Concerning emotional symptoms (assessment with OASIS and ODDIS), in general, there was a rebound at post-treatment, and a new
reduction at the 3 and 6-month follow-up. This rebound at post-treatment can be explained because the UP, as other psychological interventions, requires becoming aware of emotional responses, and this requires effort and can generate unpleasant emotions at first. With more practice over time, participants are expected to increase their tolerance of unpleasant emotions, thus reducing the frequency and intensity of emotional symptoms (e.g., Osma et al., 2015). This hypothesis is confirmed with the punctuations at the 3 and 6-month follow-up.

Statistically significant changes in neuroticism, emotional dysregulation, and emotional eating are especially relevant, considering that the factors that were most strongly associated with poor weight loss were anxiety and depression (related to neuroticism) and emotional eating (Hjelmesæth et al., 2019). Although no statistically significant differences were found, there were changes in the desired direction in dissatisfaction with body image and BMI, an aspect that is essential in this type of patients. In this sense, furthermore, the statistically significant changes in neuroticism become especially important when considering all their implications for health systems, such as the high frequency of use of general and mental health services (Lahey, 2009).

Changes in maladjustment and quality of life highlight that the intervention provides benefits beyond the emotional dysregulation itself, promoting participants’ optimal functioning. These data are also in line with previous psychological interventions carried out with this specific type of sample (Lauren et al., 2020).

Regarding extraversion, we found statistically significant differences, with medium effect size, from post-treatment to 6-month follow-up. The UP focuses on the broad range of emotions, “negative” and “positive” ones, so benefits in both dimensions of personality can be expected. However, mixed results have been found in its efficacy to increase extraversion scores in samples with EDs diagnosis, where some of them confirmed changes in extraversion (e.g., Carl et al., 2014; Tirpak et al., 2019) and others did not (e.g., Ellard et al., 2010). Some factors could explain these discrepancies, such as the small sample sizes of the studies, the different measures used, the population characteristics, or the different formats of delivery and length of the interventions.

Finally, it should be mentioned that the changes obtained on an individual level by each of the participants may have been influenced by personal characteristics or circumstances, notably among them unsatisfactory life changes (Participant 1), dysfunctional obsessive personality traits (Participant 4), or difficulty in understanding and putting into practice the different strategies learned (Participant 6). In this sense, it would be very beneficial to consider these participants’ feedback to further personalize the intervention by increasing the number of sessions or inserting individual sessions throughout the intervention.

Based on all the above-mentioned results, it is worth noting the different limitations and strengths of the present effectiveness and feasibility study.

Regarding the limitations of this study, we present data of a group including 6 participants, so the small sample size does not allow the results to be generalized, and they should be considered with caution. However, it is important to highlight that this studies are a recommendable cost-effective method to preliminarily study the effectiveness, feasibility, and/or implementation of novel intervention programs with different samples (e.g., Osma et al., 2018). It would be necessary to carry out more rigorous studies with greater control such as randomized clinical trials that allow to obtain more robust conclusions on the feasibility and effectiveness of the intervention. Furthermore, we wished to study the feasibility and effectiveness of a 9-session UP group intervention to be applied in a public mental health unit where human resources are limited. The aim proposed made it difficult to personalize the intervention to each participant’s characteristics (e.g., personality traits, difficulties in understanding the concepts, or lack of practice) and it may have limited the clinical benefits of some participants. As mentioned, the participants recommended the extension of the program sessions and the use of a mixed format, with individual and group sessions, which should be considered in future studies.

A limitation from the clinical approach was not applying modules 1 and 6 as they appear in the original version of UP. Regarding module 1, "Setting goals and maintaining motivation", in this specific case it was not applied because in the sessions prior to the intervention that each of the participants had with the clinician, they reported high motivation for change and a common goal, which was to regulate eating habits to maintain the weight achieved after BS. In these individual sessions, the clinician did explain the fundamentals of the change process, explaining the ambivalence of motivation throughout it. However, it should be noted that although the objective of people who have undergone a BS is usually to maintain weight, it is essential to personalize the objectives for each participant through the exercises in this module, identifying the steps for each of the objectives, and carrying out the exercise of the decisional balance. Furthermore, as mentioned in Table 1, it is important to add in this first module information about emotional eating and how the regulation of emotions is essential in this process, in order to understand the logic of the intervention. Regarding module 6, “Understanding and confronting physical sensations”. It was not applied because the participants in the present study did not report fear to physical sensations, however, it is important to emphasize that patients with higher scores on anxiety sensitivity will benefit the most with this module. Hunger is a very relevant physical sensation to work with this kind of participants. It would be interesting to set out adapted exercises to expose them to this sensation, to identify and tolerate it.
Another limitation identified by the participants was that the intervention could have incorporated more specific content regarding the common difficulties for patients with obesity, such as dietary aspects or physical activity. Although in the present study, the material was delivered to the participants extracted mainly from the original UP manual (Barlow et al., 2015), it would be interesting to design a specific manual, which could intersperse information about emotion-regulation strategies with information related to BS. It would also be interesting to increase the number of follow-up sessions every few months up to a minimum period of two years, as evaluating the maintenance of long-term achievements is especially relevant in this sample (Lauren et al., 2020). Finally, this study took place in a public mental health unit, so the results might not be generalizable to other contexts, such as community or social services, but having been carried out in a naturalistic context is one of the strengths of this study.

In sum, the strengths of the study are: [1] performing an emotion-regulation-based CBT intervention applied after BS, which is the type of intervention that the literature identifies as most appropriate for these patients (Helmeseth et al., 2019); [2] using an intervention focused on addressing transdiagnostic mechanisms rather than the specific symptoms of each disorder, allowing us to care for patients with comorbidity, subclinical symptomatology, and unspecified disorders, and overcoming many of the limitations of specific CBT (Barlow et al., 2017); [3] related to the previous points, using an intervention developed specifically to target neuroticism, which is a personality factor that predicts poorer BS results (Oltmanns et al., 2020) and which has been shown to have many implications for health systems (Lahey, 2009); and [4] applying the intervention in group format in a public mental health unit, which provides additional cost-effective advantages such as the reduction of waiting lists, treating more people at the same time, or enhancing social support among the participants (Yalom & Leszcz, 2005).

Conclusion

This study joins the literature that supports the versatility of the UP, adding encouraging data on its preliminary effectiveness and feasibility in post-BS patients with emotional dysregulation. In addition, it highlights the importance of psychological work in the multidisciplinary approach that must be considered to address this relevant health problem (National Health and Medical Research Council, 2013).

One of the advantages of applying this intervention is to reduce the costs associated with EDs in post-BS patients, but above all, the main advantage of applying this type of intervention in these patients is to allow a better prognosis and maintenance of the improvements obtained through the intervention (Sarver & Heinberg, 2020). In this way, we can directly address the needs of this population, responding to the psychosocial variables that revolve around BS, and offering them specialized quality care that allows them to improve their quality of life and functioning.

This study is the first step to figure out if the UP applied in group format in the public Mental Health System in Spain could be a cost-effective intervention to post-BS patients, but researchers must conduct controlled studies in the future to obtain more robust conclusions.

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