"Efficacy of ENTREN-F Program: A psycho-family and multidisciplinary intervention for children from 8 to 12 years old with childhood obesity. A controlled and randomized clinical trial"

Study Protocol

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Background

The World Health Organization (WHO, 2016) places childhood obesity as one of the greatest global challenges at the level of public healthcare. The prevalence of childhood overweight and obesity continues to rise in most countries, associated with short-term medical, psychological and social consequences that worsen in the long term (Simmonds, Llewellyn, Owen, & Woolacott, 2016; Twig et al., 2016).

The mechanisms responsible for the etiology of overweight and obesity are complex. In addition, the dynamic process in which behaviors, cognitions and emotional regulation interact with each other, together with biological parameters (i.e. genetic predisposition, energy and/or metabolic expenditure), environmental factors (i.e. eating habits, sedentary lifestyle) (Stice et al., 1999; Speiser et al., 2005), and psychological factors influence the development and maintenance of these problems. A further important psychological correlate of childhood obesity might be found in familial stress. Even though all these factors may be maintaining the problem and are predictors of a better or worse prognosis in childhood obesity interventions, emotional and family variables are still not included in this type of treatments.

Although the scientific community has been trying for some time to develop effective treatments for childhood obesity (Snethen, Broome, Treisman, Castro, & Kelber, 2016; Epstein, Paluch, Roemmich, & Beecher, 2007), there is clear evidence of the difficulty in obtaining moderate results beyond a slight weight loss (Knop et al., 2015; Skjåkødegård et al., 2014).

Recent systematic reviews have described the predictor variables for a treatment to be more effective. Specifically, treatments focused on the promotion of healthy life habits, including family participation and working from behavioral techniques, have been shown to be the most effective (Snethen et al., 2016; Altman & Wilfley, 2015; Wilfley et al., 2007). In this sense, the involvement of the family in the treatment is associated with long-term stable changes compared with other types of interventions (Wilfley et al., 2007; Epstein, Valoski, Wing, & McCurley, 1994).

Another important aspect in childhood obesity interventions is their intensity and duration. In this sense, medium-high intensities and longer durations have been associated with greater efficacy (Whitlock, O'Connor, Williams, Beil, & Lutz, 2010). Specifically, Kitzmann et al.'s (2010) review noted that with an intervention duration of around four months, the results obtained were as effective as with more extensive interventions.

Adherence to treatment is another crucial aspect in the treatment of obesity. There are studies that define which variables predict the drop-out of treatment, such as the bad relationship between parents and the child, the lack of time and motivation, the coincidence with other academic activities, the high level of family stressors, and the distance between the home and the center where the intervention is being carried out (Brennan, Walkley, & Wilks, 2012; Moroshko, 2011; Braet, Jeannin, Mels, Moens, & Van Winckel, 2010; Barlow & Ohlemeyer, 2006).

Other relevant factors that predict greater treatment effectiveness are variables such as age and gender (Moens et al., 2010; Goossens, Braet, Van Vlierberghe, & Mels, 2009), placing adolescence as a more difficult stage in which to achieve changes. Other variables include psychological problems during childhood (Moens et al., 2010; Epstein, Klein, & Wisniewski, 1994) and the degree of parental motivation (Gunnarsdottir et al., 2011; Braet et al., 2010; Moens, Braet, & Van Winckel, 2010; Braet, 2006). Despite taking into account all the previously described variables, the vast majority of treatments have focused on long-term weight reduction as the sole objective of intervention, leaving aside all these psychological and family correlates that maintain the problem.

Objetive

The main objective is to examine the effectiveness of the intervention program 'ENTREN-F' (intervention for children plus family intervention) on anthropometrics, behavior, psychological and family factors, from a multidisciplinary perspective, compared with another group participating in the same program 'ENTREN' (intervention for children without family intervention) and with a control group (usual treatment) among Spanish children with over-weight and obesity. Finally, the second aim was to evaluate whether the changes were maintained 6, 12 and 18 months after the end of the intervention.

Hyphotesis

The specific hypotheses of the present study were as follows: (a) There will be significant differences in the adherence to treatment, being higher in the ENTREN-F group (b) There will be improvements in clinical outcomes regarding the anthropometric variables of the child, the level of physical activity, psychological distress, and eating disorder of the child, after both interventions (ENTREN and ENTREN-F programme), in comparison to control group (d) There will be only improvements in clinical outcomes regarding in the family's healthy life-style, psychological distress of the parents, and the family environment, after the intervention of the ENTREN-F programme. (e) The significant changes produced will remain stable at the 6, 12 and 18-month follow-up in the ENTREN-F group.

Method

Participants and Recruitment Procedure

The sample will be made up of 240 children of 8-12 years old (IMC>P90). The dropout rate is expected to be 20%. The majority of the participants will be recruited through Primary Health Care Services, in collaboration with Pediatrics Area. Another percentage of the sample contacted the program after receiving information from their school or advertising posters.

Participation was voluntary and informed assent and consent was obtained by each participating family. Participants were told that the personal content of session discussions was confidential and should not be discussed outside the sessions.

Participants were randomly assigned to either (a) the psychofamily-based workshop program (ENTREN-F), (b) the only psychological workshop program (ENTREN) or (c) the Control Group. Participants were asked to complete questionnaires at baseline prior to the intervention (T_0), at the end of the intervention and (T_1), at 6-month follow-up (T_2), at 12-month follow-up (T_3) and at 18-month follow-up (T_4).

Design and contents

ENTREN Programme (experimental)

This intervention consists in a total of 12 biweekly sessions: 9 sessions of 2-hr only for children, with a further three 3-hr sessions attended by both families and children together: nutrition, physical activity sessions, and a closing event session. Los contenidos

de las sesiones con los niños se basan en una perspectiva cognitivo-conductual e incluyen estrategias de la entrevista motivacional. El objetivo de las sesiones con los niños es trabajar la conciencia del problema, la motivación al cambio, el concepto de salud, la regulación emocional, las habilidades sociales y autoestima. One 2-hr sesión at 6, 12 and 18-month follow-up was provided to refresh skills, their physical activity, and nutritional behaviours.

ENTREN-F Programme (experimental)

ENTREN-F has the same children's intervention than ENTREN. It has extra 6 2-hr sessions to work on family environment and communication, plus three 2-hr sessions attended by both families and children together. One 2-hr sesión at 6, 12 and 18-month follow-up was provided to refresh skills, their physical activity, and nutritional behaviours.

Control Group Programme

The intervention of this group consists in usual treatment in Primary Care provided by Endocrinology Services. 3 monthly face-to-face consultations and continous online monitoring are provided to these families, oriented to promote healthy habits of nutrition and physical activity for 6 months. It works from an exclusively behavioral perspective. We used a *token economy*, a system of contingency management based on the systematic reinforcement of target behavior.

Instruments

- **Anthropometric variables**

Nurses measured children and parents: height, weight, waist circumference and middle arm circumference. Mother and children's Body mass index (BMI) has been calculated. Participating children's BMI Z-scores was calculated according to the age and specific sex, according to the median and standard deviation, based on the data collected in the Growth Tables of Orbegozo Foundation (Sobradillo et al., 2004).

- **Lifestyle habits**

Actigraph, model GT3X. The Actigraph (Actigraph TM, LLC, Fort Walton Beach, FL, EE.UU) is a small and lightweight triaxial activity monitor/accelerometer (4,6 x 3,3 x 1,5

cm, 19 g) designed to detect accelerations ranging in magnitude from -6 a 6 g with a frequency response of 0.25–2.50 Hz. Accelerometers were programmed before handing them over to the participants and the data were recorded at a frequency of 30 Hz and reinstated to a period of 60 seconds (epoch) for analysis. The accelerometers were attached to an elastic band and rested on the child´s back. They were worn during 7 consecutive days and were only removed for water activities and sleeping. The data were downloaded and analyzed with an Actilife software (v.6.62. Actigraph TM, Pensacola, FL, USA). Level of sedentarity, light, moderated and vogorus activity (min/day) was used.

- **Child Emotional Well-being and Eating Pathology**

Clinical and standardised diagnostic interview: The Schedule for Affective Disorders and Schizophrenia for School-Age Children- Present and Lifetime version (K-SADS-PL) (Kaufman et al., 1997; De la Peña et al., 2002) is a semi-structured interview which generates DSM-IV Axis I child psychiatric diagnoses. It includes both a screening interview and supplementary questions that are administered to ascertain a diagnosis if deemed relevant. Questions were directed at the children and responses confirmed with the parents. The Spanish version of the interview (De la Peña et al., 2002) was used and the diagnoses were subsequently adapted to the DSM-5 criteria by researchers.

Depressive symptomatology (CDI; 1992; Davanzo & col, 2004): The Child Depression Inventory (CDI) (Kovacs, 2004) consists of 27 items with three response options (0 to 2). Item example: "I am always sad" or I do not like how I am". The total score of the scale ranges from 0 to 54. The internal reliability of the Spanish version was 0.69 (Davanzo, 2004). In the current sample, Cronbach´s alpha was 0.68.

Anxiety (SCAS; Spence, 1997; Bermúdez-Ornelas et al., 2010). The Spence Children Anxiety Scale is a 44 items- questionnaire related to anxiety symptoms with four Likert-type options: never (0), sometimes (1), many times (2) and always (3). It also includes 6 positive fill-in items to counteract the negative bias of the previous ones, and whose qualification is not qualified or taken into account in the analyzes. It is calibrated by the sum of the points obtained for each item. The higher the score, the more anxiety. To achieve the Spanish version, the traditional translation-retranslation procedure was used. Psychometric analyses reinforce the construct validity of this scale and show an acceptable internal consistency.

Perfectionism (CAPS; Flett et al., 2000; Castro et al., 2004). The Child and Adolescent Perfectionism Scale (CAPS) consists of 22 items that are answered on a 5-point scale, where 1 is equal to true and 5 is equal to false. It consists of two scales: Self-directed Perfectionism and Socially Pre-Written Perfectionism. In its initial validation the questionnaire reported adequate indices of internal consistency and test-retest reliability ($\alpha = 0.81$, $r = 0.74$). Similarly, with respect to the Spanish version, Castro et al. (2004) reported on internal consistency indices, Cronbach's alpha of 0.87.

Self-esteem (LAWSEQ; Lawrence, 1981; De Gracia, Marcó & Trujano, 2007). LAWSEQ is composed of 16 items with which it evaluates self-esteem in children, excluding content about image and body satisfaction. Each item is evaluated on a dichotomous scale where they should answer with YES or NO. The higher the score, the higher the personal and competence estimation.

Teasing (POTS; Thompson, JK., Cattarin, J., Fowler, B. & Fisher, E., 199; Sánchez-Carracedo et al., 2011). The Perception of Teasing Scale is a questionnaire of 11 items (Spanish version includes only 9 items) in which it is asked about different situations of ridicule and the level of associated discomfort, valued on a Likert scale with 5 options. Adequate internal consistency.

Personality Features (BFQ-NA; Barbaranelli, Caprara y Rabasca, 1998; Del Barrio et al., 2006). It is adapted from the Big Five model of personality for children and adolescents (Awareness, Openness, Extraversion, Kindness, Emotional Instability). It is a brief questionnaire (65 items that are valued using a scale of 5 alternatives). Good psychometric properties.

Child Eating Behaviour (DEBQ-C; Van Strien & Oosterverld, 2008; Baños et al., 2011). The Dutch Eating Behaviour Questionnaire is an effective instrument for the investigation of the alimentary behavior in children. The results indicate that the DEBQ-C showed an acceptable internal coherence ($a = 0.70$) and the three factors presented good adjustment indices.

Emotional Regulation (TMMS-24; Mayer y Salovey, 1997; Fernández-Berrocal, Extremera, y Ramos, 2004). The Trait Meta-Mood Scale is a trait scale of emotional meta-knowledge. Specifically, it measures the skills with which we can be aware of our own emotions, as well as our ability to regulate them. The Spanish validation can be found in Fernández.-Berrocal et al. (2004). The scale is composed of 24 items that must be scored with a Likert scale of five points (from 1 = Not at all agree, up to 5 =Strongly agree),

which are grouped in the following dimensions: perception, comprehension and regulation of emotions.

Cuestionario de percepción de estilos de crianza (CRPBI-A; Samper, P., Cortés, M. T., Mestre, V., Nácher, M. J., & Tur, A. M., 2006). The Child's Report of Parent Behaviour Inventory is a 52-item self-report questionnaire that allows to assess family discipline perceived by children from 6 to 16 years old in the relation with their mothers and with their fathers. The abbreviated form of 29 items of the questionnaire (CRPBI-A) was adapted to Spanish by Samper et al. (2006). This instrument consists of six scales that evaluate the following 6 styles of parenting practices: communicative, hostile/rejecting, controlling, permissive, overprotective, and negligent. It is suggested that CRPBI-A is an appropriate multidimensional instrument for the evaluation of parenting styles in research and clinical settings.

Adverse Childhood Events (Oliva Delgado, Jiménez Morago, Parra Jiménez, Sánchez Queija, 2008; in process of Spanish validation by ANOBAS group). It is an inventory designed to analyze the relationship between life stress events and adjustment. It consists of a list of 27 negative events related to the influential contexts during school stage (family, school and peer group).

Social stigma (WBIS; Durso & Latner, 2008; in process of validation by ANOBAS group**)** The Weight Bias Internalization Scale is an 11-item questionnaire that measures weight-related self- stigma. The scale asks participants to rate how much they agree with each statement as it applies to them on a 5-point Likert-type scale and provides scores in only one domain (e.g., "I hate myself for being overweight"). The WBIS has satisfactory internal consistency (α=.90). A higher score in the WBIS indicates a higher level of weight-related self-stigma.

- **Primary caregivers**

Depression (BDI-II; Beck, Steer & Brown, 1996; Sanz, Perdigón & Vázquez, 2003). The Beck Depression Inventory (BDI-II) (Beck, Steer & Brown, 1996). It contains 21 items measuring somatic and cognitive--affective symptoms. Higher scores indicate higher levels of depression. The BDI-II has demonstrated high internal consistency in its Spanish version (Sanz, Perdigón & Vázquez, 2003) ($\alpha = 0.87$); in the current study, it was higher (α=.92).

Personality Features (NEO Five-Factor [MRH2] Inventory - NEO-FFI; Scandell, 2000) is a shortened version of a solid empirically-validated NEO Personality Inventory-Revised, an implementation of the five-factor model (FFM) of personality.

Eating Behaviour (DEBQ ; Van Strien, Frijters, Bergers & Defares, 1986; Cebolla et al., 2014). The Dutch Eating Behaviour Questionnaire includes 3 factors: emotional eating, external eating and restriction.

Emotional Regulation (TMMS-24; Mayer & Salovey, 1997; Fernández-Berrocal, Extremera & Ramos, 2004). The Trait Meta-Mood Scale is used to evaluate the perceived emotional intelligence. The TMMS-24 (Spanish Modified Version of the Trait Meta-Mood Scale) is a trait scale of emotional meta-knowledge. Specifically, it measures the skills with which we can be aware of our own emotions, as well as our ability to regulate them. The Spanish validation can be found in Fernánde.-Berrocal et al. (2004). The scale is composed of 24 items that must be scored with a Likert scale of five points (from 1 = Not at all agree, up to 5 =Strongly agree), which are grouped in the following dimensions: perception, comprehension and regulation of emotions.

Child Feeding Questionnaire (CFQ; Birch, Fisher, Grimm-Thomas, Markey & Sawyer, 2001). It includes the scales of supervision, restriction, restriction as discipline and pressure to eat.

Expressed Emotion in family environment (FQ; Wiedemann, Rayki, Feistein, & Hahlweg, 2002; Sepúlveda et al., 2014). The Family Questionnaire was used to assess level of expressed emotion. It contains two scales, critical comments (CC) and emotional overinvolvement (EOI). For Cronbach's alpha for the CC subscale was 0.83 and 0.72 for the EOI subscale for Spanish version (Sepulveda et al., 2014). For the current study, coefficients were slightly higher (CC α = .85 and EOI, α = .76).

Family Environment (HES; Gatshall et al., 2008; Sepulveda et al., 2016). This is an obesogenic environment assessment questionnaire has 10 scales that assess the availability and accessibility of food and physical activity. To calculate the score of a scale, parents had to answer at least 75% of the items. All scales showed adequate internal consistency (α

= 0.66 to 0.84).

Escala eventos estresantes (SRRS; Holmes y Rahe, 1967). The Holmes and Rahe stress scale is a list of 43 stressful life events that can contribute to illness. Adults indicate on a dichotomous scale whether or not the different events have occurred.

Motivation to change in aspects related to obesity (design and validation of the instrument by ANOBAS group).