



ENTREN-F family-system based intervention for managing childhood obesity: Study protocol for a randomized controlled trial at primary care

Marta Rojo^{a,*}, Tatiana Lacruz^a, Santos Solano^a, Mario Vivar^a, Andrea Del Río^a,
Jone Martínez^a, Sara Foguet^a, Marta Marín^a, Alba Moreno-Encinas^a, Óscar Luis Veiga^b,
Verónica Cabanas^b, Consuelo Rey^c, Montserrat Graell^d, Ana Rosa Sepúlveda^{a,*}

^a Department of Biological and Health Psychology, Faculty of Psychology (Department of Biological and Clinical Psychology), Autonomous University of Madrid, Spain

^b Department of Physical Education, Sport & Human Motricity, Faculty of Teacher Training and Education, Autonomous University of Madrid, Spain

^c Valde las Fuentes Primary Health Care Center (Alcobendas), Public Health System from Madrid, Spain

^d Child and Adolescent Psychiatry and Psychology Department, University Hospital Niño Jesús, Centro de Investigación Biomédica en Red de Salud Mental (CIBERSAM), Madrid, Spain

ARTICLE INFO

Keywords:

Childhood obesity
Family-based intervention
Family-system-based intervention
Randomized controlled trial
Primary care
Study protocol

ABSTRACT

Background: Pediatric obesity is a primary public health concern, and designing effective programs for managing it is of the utmost importance. The objective of this study was to describe the protocol study of a three-arm, parallel, randomized controlled trial aimed at assessing the efficacy of a family-system-based intervention ("ENTREN-F" program) for managing childhood obesity, compared to the "ENTREN" program (no "F" - without specific family-system-based workshop) and a control group (behavioral monitoring).

Methods/design: The ENTREN-F program was a multicomponent family-system-based intervention carried out by a multidisciplinary team in the primary health care setting. The program targeted children between 8 and 12 years with overweight and obesity ($P \geq 85$ th). Parents were actively involved in the process. The contents were designed using the Cognitive Behavioral Therapy (CBT) principles. The program comprised individual behavioral monitoring, a healthy habits workshop for children and their parents, a CBT workshop for children, and a family-system-based workshop for parents, enhancing parental management skills plus family functioning. The trial's primary outcomes included changes in child body mass index (BMI) z-scores, child's psychological well-being, and family functioning over six months. Secondary outcomes included changes in eating behavior, physical activity, self-esteem, parental distress, parental feeding practices, and parental modeling.

Discussion: To our knowledge, this is one of the few randomized controlled trials to assess the efficacy of a multicomponent program that considers health from a comprehensive perspective, trying to improve children's psychological well-being and family functioning besides weight loss. This study, therefore, addresses a gap in the literature. If found to be efficacious, it suggests a new potential health service for translation into National Primary Health Care services in Spain, one of the ten countries with the highest prevalence of obesity in Europe.

1. Introduction

Pediatric obesity is a primary public health concern that involves current and future physical and psychological complications [1]. In Spain, 40.6% of children aged 6–9 years old are above the recommended

weight percentile for their sex and age [2]. Therefore, designing effective programs for managing childhood obesity is of the utmost importance.

In this context, multicomponent lifestyle interventions are one of the main methods for treating pediatric obesity [3]. These interventions aim

Abbreviations: RCT, randomized controlled trial; FBBT, family-based behavioral treatment; CBT, cognitive-behavioral therapy; FST, family-system-based treatment; BMI, body mass index; SES, socioeconomic status; FU, follow-up; KSADS-PL, Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version; POTS-S, Perception of Teasing Scale; LAWSEQ, Lawrence Self-Esteem Questionnaire; DEBQ-C, Dutch Eating Behavior Questionnaire-Child version; SCAS, Spence Children Anxiety Scale; CDI, Child's Depression Inventory; CFQ, Child Feeding Questionnaire; BDI-II, Beck Depression Inventory; SRSS, Short Recovery and Stress Scale; HES-S, Home Environment Survey-Spanish version; DEBQ, Dutch Eating Behavior Questionnaire.

* Correspondence to: Faculty of Psychology, Autonomous University of Madrid (UAM), Madrid, Spain.

E-mail addresses: marta.rojo@uam.es (M. Rojo), anarosa.sepulveda@uam.es (A.R. Sepúlveda).

<https://doi.org/10.1016/j.orcp.2022.07.001>

Received 7 April 2022; Received in revised form 14 June 2022; Accepted 5 July 2022

1871-403X/© 2022 The Author(s). Published by Elsevier Ltd on behalf of Asia Oceania Association for the Study of Obesity. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

to modify children's practices related to diet and physical activity, which are significant behavioral factors related to weight gain [3]. Additionally, it is fundamental to actively involve parents in the treatment process because they are essential agents of change in the child's lifestyle choices during childhood [3,4]. For instance, parents can promote positive health-related behavioral changes through practicing positive parenting skills (e.g., modeling and reinforcement) and maintaining a healthy home environment [4].

Different intervention approaches have been established, and among them, *family-based interventions* are the result of combining lifestyle interventions and active parental involvement. In this regard, systematic reviews and meta-analyses support that family-based behavioral treatments (FBBT) are the golden therapy choices for managing childhood obesity [5–9]. As the name implies, FBBT-based programs are usually rooted in a behavioral approach and involve central elements such as educational sessions on nutrition and physical activity and parental training on behavioral aspects (e.g., monitoring, goal setting, token economy, reinforcement, problem-solving, and relapse prevention) [7,8,10]. In some programs, psychoeducation on parenting styles has also been included [9].

Overall, FBBT-based programs focus on promoting health-related behaviors (e.g., increased consumption of fruit and vegetables) in the family context to achieve weight loss in children [8]. Contrary to child-focused interventions where parents play a passive role, family-based treatments recognize the influence of family and environmental contexts on a child's weight, which has been discussed in ecological models [8,11–13]. The short-term benefits of lifestyle changes and weight loss from FBBT are quite strong [9–14]. However, there is a lack of evidence for long-term positive outcomes of these programs; indeed, studies have found low or modest success rates for strategies for children's weight loss [3,15,16].

Within this context, ecological models highlight the multiple factors that may influence children's behavior, including psychological factors [11–13]. In this regard, Kang et al. stated, "Cognitive Behavioral Therapy (CBT) is a theory-based treatment approach that highlights the relationship between cognition, feelings, and behaviors and utilizes techniques involving motivational enhancement, goal-setting, problem-solving, and knowledge/skill acquisition that can facilitate sustainable behavior changes" [17]. Given this focus, supplementing behavioral approaches with techniques of CBT may help achieve positive outcomes and strengthen treatment effectiveness in pediatric weight management programs [4,7,8,17–19]. For instance, the CBT approach is the standard treatment for managing psychological manifestations related to obesity, including anxiety, negative affect, impulsivity, low self-esteem and body dissatisfaction, peer rejection, social stigmatization, disordered eating, and distorted cognitions [4,17,20]. Specifically, this intervention has proven to be effective in helping children and adolescents who have overweight or obesity to improve their health habits, reduce their weight, and achieve better psychosocial well-being [21–26].

Furthermore, some recent studies have emphasized the concept of the family as a complex and dynamic system; thus, family-based interventions should go beyond just promoting the active involvement of parents. This philosophy is at the heart of family-system-based treatments (FST) for managing pediatric obesity [27–30]. It is noteworthy that in research, children with obesity have been found to exhibit significantly higher levels of psychological difficulties and prevalence of psychiatric disorders, higher levels of maternal psychopathology, impaired family functioning, and maladaptive parental coping skills compared to their peers of normal weight status [19,30–32]. Consequently, problems within the family system that can promote weight gain must be addressed. For this purpose, in addition to parental involvement, weight management programs should include specific interventions to improve and remedy impaired family functioning, maladaptive parent-child interactions, authoritarian parental educational styles, lack of family rules or affection, family communication, or

parental distress; additionally, the interventions should provide psychological support and adaptive coping strategies for the families [8,9,29,30]. Moreover, as there is probably no one-size-fits-all approach [8], FST-based programs may be especially promising for cases that express resistance to change. In such cases, many interrelated weight-gain factors are at play, and the behavioral approach falls short.

However, a gap has been acknowledged in the potential FST-endorsed approach. Concretely, only a few studies have incorporated family system-related variables as outcomes of the interventions addressing childhood obesity, demonstrating mixed results [26–28]. In a review, Sung-Chang et al. (2013) concluded that "family-based interventions rooted in behavioral theory were more effective than those theoretically connected to family systems theory" [9]. Additionally, it should be noted that FST-based interventions are clearly understudied compared to FBBT-based interventions. For instance, only 20% of the studies in Kitzmann's review included FST-based programs [8], and there were only two FST-based programs compared to the 13 FBBT programs in Sung-Chang's systematic review [9]. Ultimately, conclusions on the potential of FST-based programs cannot be generalized, and further research is necessary [8–9].

Finding the most effective strategy for childhood obesity remains a challenge for researchers and clinical practitioners. Recent studies have published guidelines with several recommendations, including a requirement for implementing high-quality standardized protocols, and including follow-up with a longer period of 12 months to evaluate changes in the efficacy of interventions over time" [1,7,33].

Based on this background, we have designed a randomized controlled trial (RCT) study to assess the efficacy of a multicomponent family-system-based intervention rooted in the CBT principles, called "ENTREN-F". This intervention has previously been successfully piloted [26]. This program claims to actively involve both the children and parents, and it includes (i) individual behavioral monitoring, (ii) a healthy habits workshop (educational sessions on nutrition and physical activity) for managing health-related behaviors, (iii) a workshop for children aimed at improving poor psychosocial outcomes related to weight issues, and (iv) a workshop for parents to improve disruptive elements of the family system that can negatively influence the youth's behaviors and their emotional well-being and thus facilitate weight gain. This RCT will explore the efficacy of the ENTREN-F program in comparison with two group conditions: the ENTREN program (without "F", so no specific family-system-based workshop) and a control group (child-focused behavioral monitoring). These programs are carried out in primary health centers. The health context is especially important, as childhood obesity has been an increasing reason for consultation at outpatient centers. In this regard, primary care offers an ideal setting because it is the initial and the most accessible level of care for children with obesity and their families [34,35].

Concretely, this paper exhaustively describes the protocol of this clinical trial, outlining the assessment design, measures, and analytic plan for the trial. The trial's primary outcomes include changes in child body mass index (BMI) z-scores, psychological well-being in the children, and family functioning over six months. The primary hypothesis is that children in the ENTREN-F intervention group will demonstrate significantly greater reductions in BMI z-score than the comparison groups at the 6-month follow-up. Secondary outcomes related to the child include changes in eating behavior, physical activity, and for both parents, parents' BMI, emotional well-being, parental feeding practices, physical activity, and parental modeling. Sociodemographic variables, the presence of child psychiatric diagnoses, and the program adherence rates are also assessed. The maintenance of changes over time at 12, 18, and 24-month follow-ups from baseline are examined.

2. Methods

2.1. Study design

The study's design included a 3-arm randomized controlled trial comparing three group conditions: (1) the ENTREN-F program; (2) the ENTREN program; and (3) a control group (detailed below). The program was called ENTREN-F, which means "trip by train" in Spanish. The content was based on the metaphor of such a trip children and their families take, reaching different "stations" to achieve healthy habits, greater psychological well-being, and better family functioning before reaching the final destination: overall good health. The program content is illustrated in Fig. 1. The present study's protocol is drafted in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement.

2.2. Participant recruitment and eligibility criteria

Child participants were eligible if they were aged 8–12 years old and were at or above the 85th BMI percentile for their age and sex [36]. Children in this age range are assumed to have a sufficient command of writing and reading, and their lifestyle and weight trajectories are still malleable. Participation of one of the parents was a mandatory requirement. Exclusion criteria included child participants who had: a) secondary obesity caused by neurological, endocrine conditions or medication with side effects on weight, b) a mental disorder with serious severity at the time of evaluation that required immediate attention (time-sensitivity intervention), c) any brain disease or injury that hinders growth, intellectual disability, autism spectrum disorder or prolonged immobility that restricts age-appropriate play, d) children or parents did not have a fluent spoken, reading, and written command of the Spanish language, which was a requirement for completing the assessment process. The research team reviewed which child was included or excluded in the study in weekly meetings coordinated by the principal investigator (A.R.S., co-author). Participation was voluntary and free of charge for all the participants. They did not receive any financial remuneration for participating.

The recruitment plan included the collaboration of pediatricians and nurses providing outpatient care in 25 primary care centers and two hospitals of the Spanish public health service (city of Madrid). Healthcare professionals were primarily responsible for providing response flyers with information about the program for the families at routine check-ups. In addition, advertising posters with email/phone contact

information were visible in the areas surrounding the health centers so that families could contact the research team directly if they were interested in the study. It is noteworthy that all Spanish people belong to the public health system (free medical care). Recruitment started in January 2017 and ended in March 2020. Although the stop recruitment rule was to reach the expected sample, this was not possible due to the COVID-19 situation that forced us to stop recruiting new participants. When the families provided their consent, the nurses and pediatricians sent the research team the basic information of each participant (date of birth, weight, height, contact number, and relevant medical/psychiatric history). This information was subsequently verified with the families via phone by a trained research team member (A.G.) who did not participate in the intervention program and who was tasked with screening for eligibility and setting appointments with the families. All families were informed about data collection, and the child's written assent and parent-signed written informed consent were collected before randomization took place. Eligible families who consented to enroll in the study were randomized to a treatment arm. Table 1 summarizes several demographic characteristics of the families.

The calculation of the sample size was based on the child's BMI as the primary outcome variable. Assuming a two-tailed test, $\alpha = 0.05$, a power ($1-\beta$) of .80, and an effect size of .20, applying a correction of according to the guidelines of Brownell et al. [37] to anticipate a possible sample loss of approximately 20–25%, and based on the study by Robertson [24]. A sample size of 80 children per group was then estimated ($n = 240$). Sample size calculation was verified by a power analysis using G*Power (version 3.1) [38]. As mentioned, due to the COVID-19 pandemic, recruitment ended earlier than expected, obtaining a final sample of 165 participants.

2.3. Randomization

Two lead researchers (M.R. and T.L., co-authors) were responsible for carrying out a simple randomization procedure (a computer-generated list of random numbers using SPSS, version 24). As it is a single-blind study, the participants were randomized after all the children and parents completed the baseline assessment. Neither the participants nor the researchers knew which trial condition the participants would be allocated to prior to randomization. The basic information required for randomization (weight/height, initials, and participant code) was stored in a database.

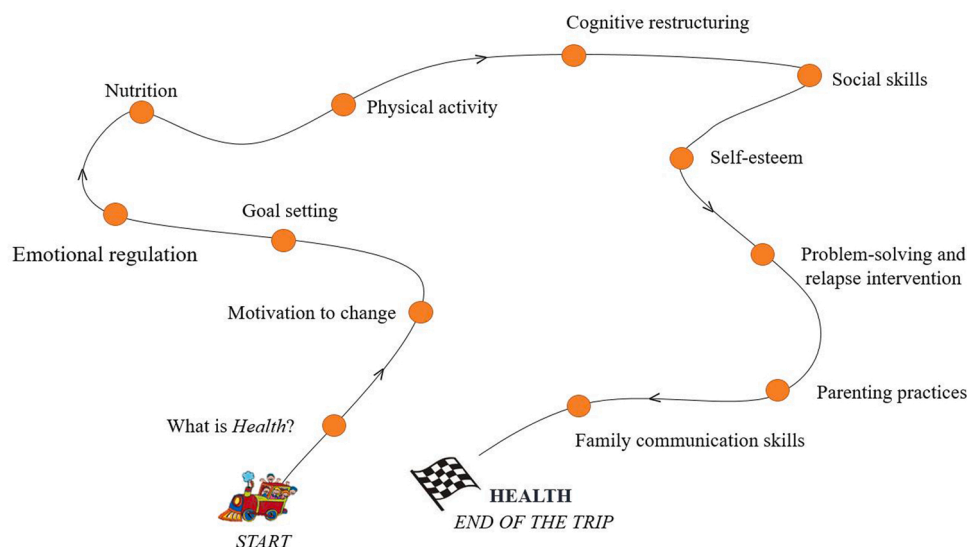


Fig. 1. Stations/stops of the ENTREN-F program.

Table 1

Baseline demographics of the families served by the ENTREN-F, ENTREN programs, and the control group in the ENTREN-F trial.

	Total	ENTREN-F Program	ENTREN Program	Control group	p
<i>Number of children served</i>	165	62	52	51	
<i>Child sex, % (n)</i>					.66
Female	42.7 (70)	45.16 (28)	44.23 (23)	37.25 (19)	
Male	57.6 (96)	54.84 (34)	55.77 (29)	62.75 (32)	
<i>Child age, years (SD)</i>	10.32 (1.42)	10.21 (1.40)	10.40 (1.51)	10.38 (1.39)	.73
<i>Child BMI z-score (SD)</i>	3.13 (1.37)	3.26 (1.30)	3.24 (1.37)	2.83 (1.47)	.21
<i>Family SES, % (n)</i>					.86
Low	36.1 (52)	32.1 (18)	37.8 (17)	39.5 (17)	
Medium	32.6 (47)	32.1 (18)	35.6 (16)	30.2 (13)	
High	31.3 (45)	35.7 (20)	26.7 (12)	30.2 (13)	
<i>Family type, % (n)</i>					.70
Two-parent family	67.4 (97)	67.9 (38)	63.0 (29)	71.4 (30)	
Single parent	32.6 (47)	32.1 (18)	37.0 (17)	28.6 (12)	
<i>Mother educational level, % (n)</i>					.16
Primary education	13.4 (17)	7.8 (4)	13.2 (5)	21.1 (8)	
High School/Technical training	59.1 (75)	62.7 (32)	68.4 (26)	44.7 (17)	
Degree/Diploma or Postgraduate	27.6 (35)	29.4 (15)	18.4 (7)	34.2 (13)	
<i>Father educational level, % (n)</i>					.87
Primary education	17.4 (20)	17 (8)	24.2 (8)	11.4 (4)	
High School/Technical training	71.3 (62)	53.2 (25)	45.5 (15)	62.9 (22)	
Degree/Diploma or Postgraduate	28.7 (33)	29.8 (14)	30.3 (10)	17.6 (9)	

Note. BMI = body mass index; SES = socioeconomic status calculated based on the Hollingshead index; The significant p-value was set at .05.

2.4. Intervention

2.4.1. ENTREN-F program

The ENTREN-F program is a multicomponent family-system-based program that utilized a CBT approach. The sessions combined proven elements from previous weight management programs such as the “LEARN Program for Weight Management”, in which the author proposed an approach to treat obesity from five main dimensions: lifestyle, physical activity, health attitudes, social relationships, and nutrition [37], and “Families for Health”, in which the authors emphasized the role of parenting, relationship skills, and emotional and social development [24]. Likewise, motivational interviewing was used in our study, as it is a psychological technique that has shown promising results in childhood obesity [39]. The intervention was done biweekly in the evening (6–8 pm) in a group setting (group size: 8–12 children), and it comprised parallel programs for children aged 8–12 years old with overweight/obesity and their parents. The ENTREN-F program consisted of the following components (Fig. 2):

- **Behavioral monitoring.** This module included four face-to-face individual counseling sessions (1 hr) aimed at implementing among children daily healthy practices associated with weight loss (e.g., increased consumption of fruits and vegetables, regulation of food intake, increased physical exercise and reduced sedentary time, and control of screen time). Families were trained in the application of the token economy technique, which was intended to be applied at home. The token economy technique is a method for strengthening a desired behavior or increasing its frequency throughout the day (e.g., encouraging fruit and vegetable consumption). Parents can positively reinforce their children’s behavior by giving them a certain number of tokens, and then, these tokens can be exchanged for rewards [40]. These sessions were conducted by psychologists who specialize in behavioral therapy. The sessions were complementary to the other modules of the ENTREN-F program and were carried out during the six months of treatment.
- **Healthy habits workshop.** It included two educational sessions on nutrition and physical activity for children and parents based on group dynamics and motivational interviewing. These workshops drew on the nutritional and physical recommendations of the United States Preventive Services Task Force (USPSTF) [41]. The physical

ENTREN-F	ENTREN	CONTROL GROUP
Behavioral monitoring Four sessions (1hr) = 4hr	Behavioral monitoring Four sessions (1hr) = 4hr	Behavioral monitoring Four sessions (1hr) = 4hr
Lifestyle intervention Nutrition session (2hr) Physical Activity session (2 hr) – Both sessions for children and parents = 4hr	Lifestyle intervention Nutrition session (2hr) Physical Activity session (2 hr) – Both sessions for children and parents = 4hr	
CBT workshop for children 10 sessions (2 hr) = 20 hr	CBT workshop for children 10 sessions (2 hr) = 20 hr	
CBT Family-system based workshop Six sessions (2-hr) = 12 hr		

Duration of the program in the three trial arms: 6 months

Fig. 2. Type of intervention among the groups targeted.

activity module was a two-hour workshop that informed participants about the importance of physical activity and its effects on health, highlighted the difference between sedentary behavior and physical activity, and described factors that facilitate and hinder active behaviors. Additionally, the workshop included a self-assessment of the level of physical activity done and sedentary behaviors practiced and provided recommendations to the youth regarding performing physical activity and strategies to increase levels of physical activity in the family. Ultimately, the nutrition workshop aimed to train and promote changes in dietary habits. For this purpose, nutrition recommendations were provided. The parents and children tried to identify barriers (e.g., food available at home, food prices, emotions, time to cook, and parental modeling) that could negatively affect eating patterns at the family level, and alternative strategies were taught in response to risky eating behaviors (e.g., snacking, emotional eating, and overeating episodes).

- **Cognitive-Behavioral Workshop for children.** This component consisted of 10 biweekly two-hour group sessions. These sessions aimed to address psychological issues frequently present in children with obesity. First, motivations for changing one's behavior were addressed. Specifically, the participating children discussed the importance of health (physical and mental health) and ideas on how to take care of it on a day-to-day basis. The children reflected on the benefits and disadvantages of making or not making changes, and they set personal goals. Then, the participants learned to identify the characteristics and functions of the primary emotions and emotional regulation strategies (e.g., belly breathing exercise and positive visualization technique). This therapy also included cognitive restructuring to modify irrational/dysfunctional beliefs into more realistic and rational ones. Additionally, the sessions worked on developing social and problem-solving skills (e.g., coping strategies in the face of peer teasing) and addressed concepts of self-esteem and body image. Finally, the workshop worked on relapse prevention (see Table 2). The sessions included interactive activities with the children, games, worksheets to complete, guided discussions, experiential exercises, etc. After each session, the team provided take-home resources (a summary sheet of the session and a review activity) for the children, to facilitate continuity of the work carried out in the session and ensure that family members had access to the material.

- **Family-system group workshops.** This component consisted of six two-hour family-group sessions based on a family-system approach. The content of the program was aimed at improving family awareness of obesity as a health concern. Moreover, it reinforced family resources such as the behavioral parenting strategies of goal setting and the application of a token economy, parental educational styles, parental feeding practices, communication skills, and adaptive dynamics in the home environment (Table 3). These sessions were held in a separate room at the same time as the children's sessions. The invitation to the family sessions was extended to the different members of the family.

Overall, randomized participants in ENTREN-F condition received a total of 40 h of intervention over six months.

2.4.2. Comparison conditions

2.4.2.1. The ENTREN program. As can be seen in Fig. 2, the ENTREN group received the same intervention as the ENTREN-F group, except that the parents did not attend the family-system group workshops. In the ENTREN program, parents were involved as agents of change in their children's health behavior by attending education sessions on physical activity and nutrition and undergoing behavioral counseling to promote healthy habits. By contrast, variables of the family system were not

Table 2

Content and dynamics of the lifestyle and psychological workshops for children.

Workshops	Learning objectives
1. Preparation of our train trip to our new destination (child and parents together)	<ul style="list-style-type: none"> – Establishing initial contact through two group dynamics ("pass the ball" and "I'm a journalist"). – Material delivery. – Increasing awareness: what is health, and why is it important in our daily life? – Presentation of the four general modules (nutrition and physical activity, emotional regulation, social skills, and self-esteem).
2. Choosing our destination (part 1)	<ul style="list-style-type: none"> – Setting personal goals ("How would I like to be when I grow up?"). – Increasing awareness: discuss the role that "health wheels" of the train play in our present and our future. – Addressing ambivalence to change (What is the best and worst part of changing?).
3. Choosing our destination (part 2)	<ul style="list-style-type: none"> – Helping build a habit step by step ("the ladder of change"). – Becoming aware that changing habits requires time and training. – Identification of barriers to change.
4. What an exciting journey!	<ul style="list-style-type: none"> – Knowing and differentiating between basic emotions (anger, joy, sadness, disgust, surprise, and fear). – Understanding one's body's reactions, thoughts, and behaviors associated with each emotion. – Learning what emotions are for; conducting an analysis of their functions on a day-to-day basis. – Understanding the role of emotions on one's journey: are they drivers or co-pilots? – Researching about one's emotions: record self-reported emotions by self-registration techniques.
5. Nutrition in my life (child and parents together)	<ul style="list-style-type: none"> – Promoting knowledge of healthy eating habits. – Explaining different eating patterns as an animal metaphor (binge eating, snacking, emotional eating, restriction, eating disorganized meals). – Setting personal nutrition goals as a family. – Reassessing motivation and barriers in their nutrition as a family.
6. Enjoy the landscape and relax	<ul style="list-style-type: none"> – Identifying signals of body activation and relaxation. – Noticing differences between slow and deep relaxation vs. quick and superficial relaxation. – Training in relaxation techniques (breathing and positive visualization). – Learning to slow down one's train: activation and impulsivity regulation techniques.
7. Physical activity in my life (child and parents together)	<ul style="list-style-type: none"> – Promoting knowledge of healthy physical activity habits. – Promoting self-knowledge of their sedentary behavior. – Setting personal physical activity goals. – Reassessing motivation and barriers in their health goals.
8. It all depends on how we look at things	<ul style="list-style-type: none"> – Understanding and identifying the different types of thinking, common thinking errors (metaphor of the glasses). – Understanding how thoughts influence one's emotions. – Learning the cognitive reappraisal technique to increase flexibility in thinking. – Researching about one's thoughts (self-reported registration).

(continued on next page)

Table 2 (continued)

Workshops	Learning objectives
9. Traveling friends	<ul style="list-style-type: none"> – Understanding the importance of social relationships. – Learning to differentiate between the characteristics of communication styles (aggressive, passive, and assertive). – Identification and training in assertive techniques. – Training in social skills in the face of teasing. – Promotion of healthy social networks development.
10. I am worth it!	<ul style="list-style-type: none"> – Developing self-evaluation learning skills. – Learning to value oneself positively. – Accepting one's weaknesses. – Identifying harmful self-talk and understanding how it affects one. – Normalizing giving and receiving affection.
11. On the way	<ul style="list-style-type: none"> – Identification of personal barriers that may affect health through ("the safe-deposit box of worries"). – Partaking in problem-solving training.
12. At full speed	<ul style="list-style-type: none"> – Reviewing the content. – Relapse prevention (conflict scenarios to train using newly learned skills).
12. Final destination (child and parents together)	<ul style="list-style-type: none"> – Closing event (fruit and drinks are shared). – Creating a family advertisement to spread the program using cardboard and colored pencils. – Presenting an oral slogan poster together, talking about the benefits and a call to action. – Post-intervention evaluation.

addressed from a broader perspective. Overall, randomized participants in this program received a total of 28 h of intervention over six months (Fig. 2).

2.4.2.2. Control group. The control group received the module defined above as "behavioral monitoring". This intervention consisted of four face-to-face sessions led by a psychologist aiming to promote health-related behaviors (healthy diet and active lifestyle). For this purpose, parents were also trained in the application of the token economy technique [40]. If families had any doubts, they could communicate with the research team by phone or via email. This behavioral intervention is similar to the standard outpatient usual care conducted by pediatricians in primary health care centers, which focuses on health education and the promotion of healthy habits. Overall, randomized participants in the control group received a total of four hours of intervention over six months (Fig. 2). After six months of intervention and data completion, these participants were invited to participate in the ENTREN-F program, following ethical standards.

2.4.3. Research team and study setting

Our research team was multidisciplinary (10 psychologists, a psychiatrist, a dietician-nutritionist, and two experts in physical activity). All members of the research group were specialists in the management of obesity and eating disorders and obesity. The research team members received specific training on the study protocol (recruitment, participant data collection, intervention development, and data analysis) and the application of motivational interviewing. A data dictionary with detailed descriptions of each variable of the protocol study, including the source of the variable, coding information if used and normal ranges were provided to the team researchers.

The study setting for the program was the primary health care centers, concretely, the "Valdelasfuentes" outpatient center (north of

Table 3

Content and sessions for the family workshops.

Workshops	Provider learning objectives
1. Welcome. Understanding a complex childhood obesity model	<ul style="list-style-type: none"> – Initial information on the characteristics of the program; team presentations to the participants. – Explaining the bio-psycho-social family model of obesity requiring a multidisciplinary team for the intervention (home task).
2. Factors involved in having overweight	<ul style="list-style-type: none"> – Reviewing home tasks about specific risk factors for the children with obesity in each family. – Exploring a psycho-educational approach: addressing myths related to having overweight and obesity. – Encouraging thinking related to weight and health. – Unlinking the motivation for the change and body image and body weight (home task).
3. Parental role and nurturing	<ul style="list-style-type: none"> – Identifying and understanding personal values. – Clarifying the role of parents, refreshing their own nurturing practices, and assessing their impact toward the child. – Exploring parental communication during child growth stages (infancy to preadolescents) and family dynamics.
4. What the process of behavior change is like	<ul style="list-style-type: none"> – Explaining change stages for behavior. – Searching for personal goals. – Navigating the approach of ambivalence before the change of healthy habits. – Evaluation of possible obstacles to one's own behavior change (home task).
5. Obstacles and difficulties	<ul style="list-style-type: none"> – Reviewing home tasks. – Training in communication skills and their relationship with the parental style (home task).
6. Parent communication skills	<ul style="list-style-type: none"> – Reviewing home tasks. – Learning behavior/attitude patterns for parental involvement in healthy lifestyles. – Improving family communication and rules.

Madrid), the "Las Margaritas" outpatient center (south of Madrid), and the Niño Jesús Children's Hospital (center of Madrid). These locations were chosen for convenience (availability in the afternoon during the week, space to develop group therapy, good location, and transport accessibility). We scheduled two editions (beginning in October and January of each academic year) with several parallel group intervention in the three centers. The psychological workshop for children and the family workshop for parents were led by psychologists. Delivery of a certificate of completion and follow-up quality control phone calls have also been included.

2.5. Measures and data collection

The protocol study included an evaluation at the beginning of the study (T_0), after 6 months of intervention (T_1), and subsequent follow-ups (T_2 , T_3 , T_4). The baseline assessment (T_0) included a semi-structured clinical diagnostic interview (1.5 h) with the child and at least one of the primary caregivers separately (mother mainly), conducted by a psychologist. Anthropometric data and self-reported questionnaires answered individually by parents and children were also collected (about an hour to complete). Assessment collection attempted to capture the mother's and father's data. After six months of intervention (T_1), a face-to-face assessment collection at the referral center was planned for the three groups. In addition, in the present study, four follow-up (FU) appointments were scheduled at 12 (T_2), 18 (T_3), and 24 months (T_4) from baseline, but only for the ENTREN and ENTREN-F groups. Participants who were initially allocated to the control group were invited to participate in the ENTREN-F program in accordance

with ethical standards after the initial six months. FU appointments (approximately 30–45 min long) were planned face-to-face at the outpatient care centers and were carried out by the team of psychologists. In case of unavailability, an alternative appointment via a real-time video call was possible. Likewise, FU data could be completed on paper or online (via Google Forms). The outcome measures collected are described in Tables 4 and 5. All data has been recorded in study databases which have been regularly scheduled.

2.6. Outcome measures

The trial's primary outcomes include changes in child body mass index (BMI) z-scores, psychological well-being in the children, and family functioning after 6 months of intervention comparing the three groups. Secondary outcomes related to the child include changes in eating behavior, physical activity, and for both parents, parents' BMI, other related-measures of psychological symptomatology, parental feeding practices, physical activity, and parental modeling.

2.6.1. Primary outcome measures

Child weight status. BMI z-scores were calculated according to BMI standard deviations scores varying with age and sex, based on the growth tables of the Orbegozo Foundation [36]. The heights and weights of the children are measured using a digitally calibrated scale (Type SECA 799 and 769) and a tallimeter at the Primary Health Care centers. These measures were taken by the same three trained members of the staff.

Child psychological well-being. The Children's Depression Inventory (CDI) [42], composed of 27 items with three-Likert response options, is used, with a higher score indicating greater depressive symptoms. The internal reliability for the Spanish version was $\alpha = .69$ [43]. Anxiety was assessed with the Spence Children's Anxiety Scale (SCAS) [44]. This questionnaire consists of 38 items with four-Likert response options, with higher scores indicating greater anxiety symptoms. The internal reliability for the Spanish version was $\alpha = .92$ [45].

Family functioning. The Family Questionnaire (FQ) [46] consists of 20-item parental levels of expressed emotion, defined by the levels of critical comments (CC) and emotional overinvolvement (EOI) in the communication between parents and their children. A high score of expressed emotion is considered a risk factor of weight gain. In the Spanish version, Cronbach's alpha for the CC subscale was .83 and was .72 for the EOI subscale [47].

2.6.2. Secondary outcome measures

- **Other anthropometric data.** Waist circumference was measured for children and primary caregivers. BMI of the parents is calculated by dividing the total weight (kg) by the height squared (m^2). The heights and weights of the parents were also objectively measured using a digitally calibrated scale (Type SECA 799 and 769) and a tallimeter.
- **Child self-esteem.** The Lawrence Self-Esteem Questionnaire (LAWSEQ) consists of 16 items, which evaluate self-esteem in children, excluding content about image and body satisfaction. The higher the score, the higher the personal and competence estimation [48]. The internal consistency in the Spanish version was $\alpha = 0.67$ [49].
- **Teasing.** Perception of Teasing Scale (POTS-S) [50] assesses the frequency children and young adults experience teasing. While the original scale consists of 11 items, the Spanish version includes nine of these items and the same two subscales (weight-related teasing [WRT] and competency teasing [CT]) and has demonstrated good psychometric properties ($\alpha = .86$ for WRT and .76 for CT) [51]. Participants respond to each item on a Likert scale ranging from one to five.
- **Parental psychological well-being.** Parental depression symptoms were evaluated with the Beck Depression Inventory (BDI), consisting of 21 items (on a four-point Likert scale). Higher scores indicate higher levels of depression [52]. The BDI-II has demonstrated high internal consistency in the Spanish validation ($\alpha = .87$) [53]. Parental levels of stress were measured by the Short Recovery and Stress Scale (SRSS). The SRSS includes 43 life events, each scored from 0 to 100 units of life change (ULC), where a higher score is indicative of major stress and higher chances of illness [54].
- **Parental modeling.** The Spanish-version of the Home Environment Survey-Physical Activity (HES-S) [55,56] inquired about parental modeling of the physical activity (PA) behaviors addressed in the intervention via four scales: PA Availability (22 items) and Accessibility (four items) (Cronbach's alpha = .49), Parental Role Modeling (six items) (Cronbach's alpha = .59), and Parental Policies (five items) (Cronbach's alpha = .79). Higher scores indicate higher levels of availability, accessibility of PA, parental modeling, and policies.
- **Child feeding practices (CFQ)** [57]. This questionnaire consists of 33 questions in eight subscales (perceived responsibility, perceived parent weight, perceived child weight, parent's concerns about child weight, monitoring, restriction, restriction as discipline, pressure to eat) and asks parents about their attitudes, beliefs, and practices regarding child feeding, as well as their relationship to their child's developing acceptance patterns, controls of food intake, and obesity.

Table 4
Child outcome measures collected.

Outcome measure	Method	Baseline	Post-Intervention	12-month FU	18-month FU	24-month FU
Weight status	BMI z-score	v	v	v	v	v
Physical Activity	Accelerometer	v	v			
Psychological Evaluation	K-SADS-PL	v				
Depression	Questionnaire CDI	v	v	v	v	v
Self-esteem	Questionnaire LAWSEQ	v	v	v	v	v
Teasing	Questionnaire POTS-S	v	v	v	v	
Anxiety	Questionnaire SCAS	v	v	v	v	v
Eating Behavior	Questionnaire DEBQ-C	v	v	v	v	v

Note. FU = follow-up measure from baseline; BMI = Body Mass Index; KSADS-PL = Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version; CDI = Child's Depression Inventory; LAWSEQ = Lawrence Self-Esteem Questionnaire; POTS-S = Perception of Teasing Scale; SCAS = Spence Children Anxiety Scale; DEBQ-C = Dutch Eating Behavior Questionnaire-Child version.

Table 5
Family outcome measures collected.

Outcome measure	Method	Baseline	Post-Intervention	12-month FU	18-month FU	24-month FU
Body Mass Index	BMI	v				
Demographic variables	Semi-structured interview	v				
Child feeding style	Questionnaire CFQ	v	v	v	v	
Family functioning	Questionnaire FQ	v	v	v	v	v
Depression	Questionnaire BDI-II	v	v	v	v	v
Stressful life events	Scale SRSS	v				
Family environment	Survey on the familiar environment at home (HES-S)	v	v	v	v	
Eating Behavior	Questionnaire DEBQ	v	v	v	v	v

Note. FU = follow-up measure from baseline; BMI = Body Mass Index; CFQ = Child Feeding Questionnaire; FQ = Family Questionnaire; BDI-II = Beck Depression Inventory; SRSS = Short Recovery and Stress Scale; HES-S = Home Environment Survey – Spanish Version; DEBQ = Dutch Eating Behavior Questionnaire.

Reliability was obtained through Cronbach's alpha coefficient of .86 [58].

- *Child eating behavior* (DEBQ-C) [59]. The Spanish version of the Dutch Eating Behavior Questionnaire-Child has 20 items (on a three-point Likert scale) and three subscales (emotional eating, external eating, and restrictive eating). A higher score indicates a greater presence of these eating behaviors in the child. The results indicate that the DEBQ-C showed acceptable internal consistency ($\alpha = .70$). [60]
- *Parental eating behavior* (DEBQ) [61]. The Spanish version of the Dutch Eating Behavior Questionnaire is made up of 33 items with five response options grouped into three subscales (emotional eating, external eating, and restrictive eating). A higher score indicates a greater presence of these eating behaviors in the parents. Cronbach's alphas were high for the three subscales (α between .84 and .94) [62]
- *Physical activity and sedentary time*. This measure was assessed by Actigraph accelerometers, model GT3X (ActigraphTM, Pensacola, FL, USA). Raw data were reintegrated into a 10 s epoch before analyses for adequate precision. Devices were located at the lower back, and participants were required to wear the accelerometer for seven consecutive days, removing it only for sleep and water-based activities. A minimum recording criterion of three days and 10 h per day was used to be considered valid data. Data will be analyzed with ActiLife software (v.6.62. Actigraph TM, Pensacola, FL, USA). Nonwear time was determined according to Choi's algorithm [63]. Cut-off points of 100, 2000, and 4000 cpm were used to estimate daily time in sedentary, light, and vigorous activity (min/day) [64].

Sociodemographic variables, the presence of any child psychiatric diagnosis, and the program adherence rates are also assessed as follows:

- *Sociodemographic variables*. Trained staff carried out a structured psychosocial interview with the primary parent to collect the following data about the children and their parents: sex, date of birth, level of education, job occupation, and marital status (divorced/separated/widower categorized as “un-partnered families” or “married/living together families”). Families' socioeconomic status (SES) is calculated using the Hollingshead Index [65].
- *Child psychiatric diagnoses*. The prevalence of child psychological disorders in the sample was assessed by trained interviewers using the Spanish version of the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime version (K-SADS-PL) [66] during a semi-structured interview to diagnose current and past episodes of psychopathology in children and adolescents according to the DSM-5 criteria.

- *Adherence*. The rate of participants' responses in stages prior to the intervention and the rate of attendance and attrition in the three intervention groups will be analyzed. Qualitative data on the reasons for abandonment reported by families will also be recorded.

2.7. Statistical analyses

Detailed exploratory descriptive analyses to examine the distributions of key baseline demographic variables are planned. Descriptive statistics (means, standard deviations, and percentages) of all the sociodemographic, clinical, psychological, and family variables will be calculated. A Kolmogorov-Smirnov test will be used to check for normal distribution. As some missing data is likely, a preliminary plan for missing data has also been taken into account. Intention-to-treat principles will be used with all participants analyzed in the groups that are randomized, even those participants who drop out or deviate from the trial. Analysis of variance (ANOVA) will be used to observe differences between groups at baseline. The outcomes will be assessed by comparing the differences in change over time between groups. While our main analysis will examine the effect of the ENTREN-F program on change in child BMI z-scores, psychological well-being, and family functioning, we will use the same analytic strategy for all child and parent outcomes. Due to COVID-19 pandemic, the ideal sample size has been impossible to reach. Thus, statistical analyses may have to be adjusted since the sample size will not allow the adequate power to detect statistical differences as was designed in the study. We will try to use statistical corrections to improve our results. Generalized linear mixed models will be used to analyze the data to determine differences between both groups over time (baseline, six months, and long-term follow-up). The effect size will be measured using partial eta squared (η^2), and the guidelines for interpreting this value are as follows: large effect ($\eta^2 \geq .14$); medium effect ($\eta^2 \geq .06$); and small effect ($\eta^2 \geq .01$) [67]. As there is probably no one-size-fits-all approach, potential moderators (e.g., how baseline family functioning affects treatment success) and mediators of intervention (e.g., how a change in family functioning mediates weight loss) will also be explored. The analysis of the data will be carried out using the IBM statistical software SPSS, version 26.0 for Windows. Statistical level of significance will be set at .05.

3. Conclusions

This paper details the protocol design of the ENTREN-F research project, a multidisciplinary family-system intervention based on the CBT approach for managing overweight and obesity in Spanish children between 8 and 12 years of age. To our knowledge, this is one of the few protocols of a CBT family-based program using randomized trials in

which psychosocial and family-system related factors are included as outcomes of the intervention, in addition to weight loss and changes in health-related behaviors. Concretely, in this RCT the effectiveness of three different programs (i.e., ENTREN-F, ENTREN and a control group) has been assessed. The efficacy of both programs, ENTREN and ENTREN-F were successfully tested in a pilot study before the design of the current randomized controlled trial study [26].

Previous research highlighted the importance of ensuring future research on FST-based programs for addressing childhood obesity [8,9,27–30], as well as including psychosocial-related variables in the intervention [13,19,20]. The ENTREN and the ENTREN-F programs aim to work on reinforcing health-related behaviors at the family level from a behavioral approach and the child's psychological resources using CBT therapy. Moreover, at the parental level, ENTREN-F aims to ensure that families not only have essential knowledge about nutrition, physical activity, and behavioral management skills but also new resources to improve the emotional climate and functioning in the family. As mentioned in the introduction section, this is important since children with obesity present a higher risk of presenting psychological difficulties and growing up in a more discordant family environment, compared to their peers with normal weight [19,31,32].

The recruitment and data collection of the present study are already finished. Several limitations in the design of this study are worth noting. The recruitment of the sample and the development of the intervention groups were paralyzed because of the COVID-19 pandemic, this has led to limitations when it comes to reaching the ideal sample. Additionally, as the sample size will not allow adequate power, statistical analyses may not be able to detect the effects of the ENTREN-F intervention, and may have to be adjusted, as evidenced by the power calculations stated earlier in the study design. Consequently, generalization of the results may be limited. Thus, we will practice caution with the plan to make recommendations related to the intervention.

Other potential drawback is that the effectiveness of the control group was assessed after six months of intervention but not in later periods, while the other two intervention groups were followed up for two years; thus, this will hinder the ability to compare treatments for the long term. Additionally, our program was aimed at children with overweight and obesity; however, most of our participants have moderate or severe obesity. Recent research has discussed quite eloquently that reporting the BMI z-score is not recommended in children whose BMI is > 95th percentile [68–70]. Our program was designed to target children who had overweight or obesity ($P \geq 85$ th). After completing the recruitment, most of our sample included children with BMI values above the 95th percentile. Following experts' recommendations, we will report complementary weight-related measures such as the percent of the 95th percentile (PCT95), which have been identified as metrics with better specificity for youth with severe obesity. Moreover, the requirement for the intervention included the attendance of one parent, and this can result in the participation of only one of the primary caregivers. The assessors were not blinded during follow-up visits, and the use of self-reported measures may also carry a possible bias in responses.

This study has a number of strengths, in accordance with recent recommendations for conducting high-quality childhood research studies with families [2,33]. A long-term follow-up (24-month from baseline) will determine if the changes of the ENTREN and ENTREN-F intervention can be maintained. The team was multidisciplinary, and all members received specific training on the protocol study. Program facilitators had experience implementing good practices relating to family-based interventions, such as behavioral therapy and motivational interviewing strategies [1]. A plan was drawn up to optimize the recruitment of participants, the evaluation phase, intervention, and adherence to treatment. For example, the intervention was free of charge for all the participants, and it was carried out in Primary Health Care, the most accessible level of care for children with obesity and their families. Moreover, multiple objective and valid data collection methods were used to obtain the predicted outcome measures, and our evaluation

protocol included data collection of both mothers and fathers. This is important due to the underestimated representation of fathers in family interventions on childhood obesity [71,72].

Despite the mixed results of previous literature [9], we are optimistic that the ENTREN-F program can produce positive results in child weight and weight-related behaviors, as well as parenting practices, family functioning, and emotional well-being. This is important because not all the treatments are equally effective for everyone (within-group differences), and ENTREN-F may be especially beneficial for families with impaired functioning, which are more resistant to change and may be limited by an exclusive behavioral approach. Overall, findings from this study may contribute to advancements in both scientific research and medical practice in childhood obesity, also updating the limited literature on CBT family-system interventions on pediatric weight management treatment in health systems. If this program is found to be successful, a new potential health service can be created and translated into the Nationwide Primary Health Care services in Spain to tackle its current standing as one of ten countries with the highest prevalence of obesity in Europe.

4. Ethics and dissemination

4.1. Confidentiality

All the study records are confidential and will not be shared outside the immediate research team, including sponsoring organizations. Following the Organic Law 3/2018 of Protection of Personal Data and guarantee of digital rights, the data collected are anonymized with a number code to ensure participant confidentiality. The Spanish Ministry of Economy, Industry, and Competitiveness provides annual quality assurance for monitoring and auditing all financial projects (four-year). This plan addresses data validation and registry procedures.

4.2. Ethics and governance

The current study received ethical approval from the Niño Jesús Children's Hospital (Ref 0058–16), Primary Care Commission (Ref. 32/17), and the University Committee (UAM, Research Ethics Committee CEI-76–1394), certifying that the study was performed by the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

4.3. Withdrawal

Patients are informed of their right to withdraw from the study without explanation at any time. In case of patient withdrawal, they will be asked for later use of their record data.

Funding

This study was funded by the Spanish Ministry of Science and Innovation (RETOS PSI2016-79471-R). Partial financial support was received from the "Auchan Foundation for Youth" and the "Promotion of Knowledge Transfer" of the UAM-Foundation (2019-ES-00067). Ms. Rojo was awarded a Research Fellowship (FPU) for students of Ph.D. Programs from the Spanish Ministry of Science and Innovation (FPU2017/02840).

Conflict of interest

No authors have any competing interests.

Data Availability

The study protocol will be made available, with the structure of the program and the specific content of the sessions published in a

guidebook. Upon prior request, a document with the interpretation of the items in SPSS databases, a description of the instruments and outcomes variables included in this study, may also be provided. Dr. Sepúlveda is responsible for reviewing all requests and making the final decision. Our criteria involve requests sent by national and international research groups related to childhood obesity or eating disorders using a replica of ENTREN's RCT in other countries or meta-analyses studies. Data will be collected and stored on the university server, which will be protected by a password to prevent unintentional modification or deletion.

Acknowledgments

This study was selected by the Ministry for Science and Innovation to receive a grant under the framework of the National R&D&I Plan (RETOS PSI2016-79471-R). We gratefully acknowledge the Ministry for Science and Innovation for supporting the Ph.D. scholarship of one of the lead researchers (M.R.) during this study. We would like to acknowledge the implication of the pediatricians and nurses providing outpatient care in the several health centers from the Public Health System of the Community of Madrid (Spain) who accepted our invitation to collaborate in this study. Likewise, to the expert professionals in charge of developing the nutrition module (J. Adán). The authors would also like to thank J.A. Martínez-Huertas, who advised us with the plan for statistical analyses.

Author contributions

A.R.S. is the principal investigator and is responsible for the overall direction and conduct of the study. A.R.S. conceived the study along with co-investigators T.L., S.S., M.R., and M.G. Moreover, T.L. and S.S. participated in intervention design, and T.L. designed all the intervention artwork. M.R. is a Ph.D. student and managed the day-to-day running of the study and data collection, contributed to program content, and drafted and led the preparation of this manuscript, supervised by A.R.S. Further, M.G. and C.R. coordinated the access to health centers and participated in the recruitment of participants from Primary Care. O.V. and V.C. were in charge of the accelerometry data collection and the module of physical activity. All the authors (M.R., T.L., S.S., M.V., A.D., J.M., S.F., M.M., A.M., O.L.V. V.C., C.R., M.G., A.R.) participated in the intervention design and survey participation and have reviewed, edited, and approved the manuscript.

References

- Quattrin T, Wilfley DE. The promise and opportunities for screening and treating childhood obesity: USPSTF recommendation statement. *JAMA Pediatr* 2017;171(8):733–5. <https://doi.org/10.1001/jamapediatrics.2017.1604>.
- Agencia Española de Seguridad Alimentaria y Nutrición, Estudio ALADINO 2019: Estudio sobre Alimentación, Actividad Física, Desarrollo Infantil y Obesidad en España 2019; 2002. (<https://www.aesan.gob.es/AECOSAN/web/nutricion/detalle/aladino.2019.htm>).
- Reinehr T. Lifestyle intervention in childhood obesity: changes and challenges. *Nat Rev Endocrinol* 2013;9(10):607–14.
- Wilfley DE, Kolko RP. Cognitive-behavioral AE. therapy for weight management and eating disorders in children and adolescents. *Child Adolesc Psychiatr Clin* 2011;20(2):271–85.
- Ash T, Agaronov A, Young TL, Aftosmes-Tobio A, Davison KK. Family-based childhood obesity prevention interventions: a systematic review and quantitative content analysis. *Int J Behav* 2017;14(1):1–12. <https://doi.org/10.1186/s12966-017-0571-2>.
- Berge JM, Everts JC. Family-based interventions targeting childhood obesity: a meta-analysis. *Child Obes* 2011;7(2):110–21. <https://doi.org/10.1089/chi.2011.07.02.1004.berge>.
- Chai LK, Collins C, May C, Brain K, See DW, Burrows T. Effectiveness of family-based weight management interventions for children with overweight and obesity: an umbrella review. *JBI Evid Synth* 2019;17(7):1341–427. <https://doi.org/10.11124/JBISIR-2017-003695>.
- Kitzmann KM, Beech BM. Family-based interventions for pediatric obesity: methodological and conceptual challenges from family psychology. *Couple Fam Psychol* 2011;1(S):45–62. <https://doi.org/10.1037/2160-4096.1.S.45>.
- Sung-Chan P, Sung YW, Zhao X, Brownson RC. Family-based models for childhood obesity intervention: a systematic review of randomized controlled trials. *Obes Rev* 2013;14(4):265–78. <https://doi.org/10.1111/obr.12000>.
- Enright, G. Combating childhood obesity: discovery and translation of evidence for new strategies to enhance behaviour change (Doctoral dissertation). University of Sydney; 2020.
- Harrison K, Bost KK, McBride BA, Donovan SM, Grigsby-Toussaint DS, Kim J, et al. Toward a developmental conceptualization of contributors to overweight and obesity in childhood: the Six-Cs model. *Child Dev Perspect* 2011;5(1):50–8. <https://doi.org/10.1111/j.1750-8606.2010.00150.x>.
- Hemmingson E. A new model of the role of psychological and emotional distress in promoting obesity: conceptual review with implications for treatment and prevention. *Obes Rev* 2014;15(9):769–79. <https://doi.org/10.1111/obr.12197>.
- Smith JD, Egan KN, Montaña Z, Dawson-McClure S, Jake-Schoffman DE, Larson M, et al. A developmental cascade perspective of paediatric obesity: a conceptual model and scoping review. *Health Psychol Rev* 2018;12(3):271–93. <https://doi.org/10.1080/17437199.2018.1457450>.
- Sacher PM, Kolotourou M, Chadwick PM, Cole TJ, Lawson MS, Lucas A, et al. Randomized controlled trial of the MEND program: a family-based community intervention for childhood obesity. *Obesity* 2010;18(1):S62–8. <https://doi.org/10.1038/oby.2009.433>.
- Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year outcomes of behavioral family-based treatment for childhood obesity. *Health Psychol* 1994;13(5):373. <https://doi.org/10.1037/0278-6133.13.5.373>.
- Kolotourou M, Radley D, Gammon C, Smith L, Chadwick PM. Long-term outcomes following the MEND 7–13 child weight management program. *Child Obes* 2015;11(3):325–30. <https://doi.org/10.1089/chi.2014.0092>.
- Kang NR, Kwack YS. An update on mental health problems and cognitive behavioral therapy in pediatric obesity. *Pediatr Gastroenterol Hepatol Nutr* 2020;23(1):15–25.
- Pratt KJ, Skelton JA. Family functioning and childhood obesity treatment: a family systems theory-informed approach. *Acad Pediatr* 2018;18(6):620–7. <https://doi.org/10.1016/j.acap.2018.04.001>.
- Blanco M, Sepúlveda AR, Lacruz T, Parks M, Real B, Martín-Peñador Y, et al. Maternal psychopathology, family functioning and coping skills in childhood obesity: a case-control study. *Eur Eat Disord Rev* 2017;25(5):359–65. <https://doi.org/10.1002/erv.2527>.
- Baile Ayensa JI, González-Calderón MJ, Palomo Santos R, Rabito-Alcón MF. La intervención psicológica de la obesidad: desarrollo y perspectivas. *Rev Clín Contemp* 2020;11(1):1–14. <https://doi.org/10.5093/cc2020a1>.
- Baños RM, Oliver E, Navarro J, Vara MD, Cebolla A, Lurbe E, et al. Efficacy of a cognitive and behavioral treatment for childhood obesity supported by the ETIOBE web platform. *Psychol Health Med* 2019;24(6):703–13. <https://doi.org/10.1080/13548506.2019.1566622>.
- Freitas CR, Gunnarsdóttir T, Fidelix YL, Tenório TR, Lofrano-Prado MC, Hill JO, et al. Effects of a psychological intervention on the quality of life of obese adolescents under a multidisciplinary treatment. *J Pediatr* 2017;93:185–91. <https://doi.org/10.1016/j.jpeds.2016.05.009>.
- Miri SF, Javadi M, Lin CY, Griffiths MD, Björk M, Pakpour AH. Effectiveness of cognitive-behavioral therapy on nutrition improvement and weight of overweight and obese adolescents: a randomized controlled trial. *Diabetes Metab Syndr Clin Res Rev* 2019;13(3):2190–7. <https://doi.org/10.1016/j.dsx.2019.05.010>.
- Robertson W, Friede T, Blissett J, Rudolf MC, Wallis M, Stewart-Brown S. Pilot of “Families for Health”: community-based family intervention for obesity. *Arch Dis Child* 2008;93(11):921–8. <https://doi.org/10.1136/adc.2008.139162>.
- Roth B, Munsch S, Meyer AH. Long-term evaluation of a psychological training for obese children and their parents (TAKE). *Prax Kinderpsychol Kinderpsychiatr* 2011;60(4):304–21. <https://doi.org/10.13109/prkk.2011.60.4.304>.
- Sepúlveda AR, Solano S, Blanco M, Lacruz T, Veiga O. Feasibility, acceptability, and effectiveness of a multidisciplinary intervention in childhood obesity from primary care: Nutrition, physical activity, emotional regulation, and family. *Eur Eat Disord Rev* 2020;28(2):184–98. <https://doi.org/10.1002/erv.2702>.
- Flodmark CE, Ohlsson T, Ryden O, Sveger T. Prevention of progression to severe obesity in a group of obese school children treated with family therapy. *Pediatrics* 1993;91:880–4.
- Kitman-Ulrich H, Wilson DK, St George SM, Lawman H, Segal M, Fairchild A. The integration of a family systems approach for understanding youth obesity, physical activity, and dietary programs. *Clin Child Fam Psychol Rev* 2010;12(3):231–53. <https://doi.org/10.1007/s10567-010-0073-0>.
- Pratt KJ, Skelton JA. Family functioning and childhood obesity treatment: a family systems theory-informed approach. *Acad Pediatr* 2018;18(6):620–7.
- Skelton JA, Van Fossen C, Harry O, Pratt KJ. Family dynamics and pediatric weight management: putting the family into family-based treatment. *Curr Obes Rep* 2020;9(4):424–41. <https://doi.org/10.1007/s13679-020-00407-9>.
- Halliday JA, Palma CL, Mellor D, Green J, Renzaho AMN. The relationship between family functioning and child and adolescent overweight and obesity: a systematic review. *Int J Obes* 2014;38(4):480–93. <https://doi.org/10.1038/ijo.2013.213>.
- Sepúlveda AR, Blanco M, Nova E, Marcos A, Martínez SG, Carroles JA, et al. Identifying the relationship between biological, psychosocial and family markers associated with childhood obesity: case-control “ANOBAS” study. *Psychoneuroendocrinology* 2019;110:104428. <https://doi.org/10.1016/j.psyneuen.2019.104428>.
- Morgan PJ, Jones RA, Collins CE, Hesketh KD, Young MD, Burrows TL, et al. Practicalities and research considerations for conducting childhood obesity prevention interventions with families. *Children* 2016;3(4):24. <https://doi.org/10.3390/children3040024>.

- [34] Ariza C, Ortega-Rodríguez E, Sánchez-Martínez F, Valmayor S, Juárez O, Pasarín MI, et al. La prevención de la obesidad infantil desde una perspectiva comunitaria. *Aten Prima* 2015;47(4):246–55. <https://doi.org/10.1016/j.aprim.2014.11.006>.
- [35] Fernández ME, Segura ME. Manejo práctico del niño obeso y con sobrepeso en *Pediatría de Atención Primaria*. *Foro Pediatr* 2005;Suppl. 2(1):S60–9.
- [36] Sobradillo B, Aguirre A, Aresti U. Curvas y tablas de crecimiento. *Estudios longitudinal y transversal*. Bilbao: Fundación Faustino Orbeago, Bilbao; 2004.
- [37] Brownell, K. The LEARN program for weight management. American Health Publishing Company. Dallas, TX; 2004. ISBN 13: 9781878513243.
- [38] Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G* Power 3.1: tests for correlation and regression analyses. *Behav Res Methods* 2009;41(4): 1149–60. <https://doi.org/10.3758/BRM.41.4.1149>.
- [39] Borrello M, Pietrabissa G, Ceccarini M, Manzoni GM, Castelnovo G. Motivational interviewing in childhood obesity treatment. *Front Psychol* 2015;6:1732. <https://doi.org/10.3389/fpsyg.2015.01732>.
- [40] Hackenberg T. Token reinforcement: a review and analysis. *J Exp Anal Behav* 2009;91:257–86. doi:10.1901/jeab.2009.91.257.
- [41] US Preventive Services Task Force. Screening for obesity in children and adolescents: US Preventive Services Task Force recommendation statement. *JAMA*. (10.1001/jama.2017.6803).
- [42] Kovacs, M. Children's depression inventory (CDI). Toronto: Multi-Health System; 2003.
- [43] Davanzo P, Kerwin L, Nikore V, Esparza C, Forness S, Murrelle L. Spanish translation and reliability testing of the child depression inventory. *Child Psychiatry Hum Dev* 2004;35(1):75–92. <https://doi.org/10.1023/b:chud.0000039321.56041.cd>.
- [44] Spence SH, Barrett PM, Turner CM. Psychometric properties of the Spence Children's Anxiety Scale with young adolescents. *J Anxiety Disord* 2003;17(6): 605–25. [https://doi.org/10.1016/S0887-6185\(02\)00236-0](https://doi.org/10.1016/S0887-6185(02)00236-0).
- [45] Godoy A, Gavino A, Carrillo F, Cobos MP, Quintero C. Composición factorial de la versión española de la Spence Children Anxiety Scale (SCAS). *Psicothema* 2011;17 (6):289–94.
- [46] Wiedemann G, Rayki O, Feinstein E, Hahlweg K. The family questionnaire: development and validation of a new self-report scale for assessing expressed emotion. *Psychiatry Res* 2002;109(3):265–79. [https://doi.org/10.1016/S0165-1781\(02\)00023-9](https://doi.org/10.1016/S0165-1781(02)00023-9).
- [47] Sepúlveda AR, Anastasiadou DT, Rodríguez Santos L, Vaz Leal FJ, Graell M. Spanish validation of the Family Questionnaire (FQ) in families of patients with an eating disorder. *Psicothema* 2014;26(3):321–7. <https://doi.org/10.7334/psicothema2013.310>.
- [48] Lawrence D. The development of a self-esteem questionnaire. *Br J Educ Psychol* 1981;51(2):245–51. <https://doi.org/10.1111/j.2044-8279.1981.tb02481.x>.
- [49] De Gracia M, Marcó M, Trujano P. Factores asociados a la conducta alimentaria en preadolescentes. *Psicothema* 2007;19(4):646–53.
- [50] Thompson JK, Cattarin J, Fowler B, et al. The perception of teasing scale (OTS): a revision and extension of the physical appearance related teasing scale (PARTS). *J Pers Assess* 1995;65:146–57.
- [51] López-Guimerà G, Fauquet J, Sánchez-Carracedo D, Barrada JR, Saldaña C, Masnou-Roig A. Psychometric properties of the perception of teasing scale in a Spanish adolescent sample: POTS-S. *Eat Weight Disord* 2012;17(3):210–8. <https://doi.org/10.3275/8245>.
- [52] Beck AT, Steer RA, Brown GK. Beck depression inventory. New York: Harcourt Brace Jovanovich; 1987.
- [53] Sanz J, Perdigón AL, Vázquez C. Adaptación española del Inventario para la Depresión de Beck-II (BDI-II): 2. Propiedades psicométricas en población general. *Clin Salud* 2003;14(3):249–80.
- [54] Blasco-Fontecilla H, Delgado-Gómez D, Legido-Gil T, De Leon J, Pérez-Rodríguez MM, Baca-García E. Can the Holmes-Rahe social readjustment rating scale (SRRS) be used as a suicide risk scale? An exploratory study. *Arch Suicide Res* 2012;16(1):13–28. <https://doi.org/10.1080/13811118.2012.640616>.
- [55] Gattshall ML, Shoup JA, Marshall JA, Crane LA, Estabrooks PA. Validation of a survey instrument to assess home environments for physical activity and healthy eating in overweight children. *Int J Behav Nutr Phys Act* 2008;5(1):1–13. <https://doi.org/10.1186/1479-5868-5-3>.
- [56] Sepúlveda AR, Blanco M, Solano S, Lacruz T, Román FJ, Parks M, et al. The Spanish version of the Home Environment Survey (HES) among families of children with overweight/obesity: a validation study. *Eat Weight Disord* 2021;26(7):2153–63. <https://doi.org/10.1007/s40519-020-01056-6>.
- [57] Birch LL, Fisher JO, Grimm-Thomas K, Markey CN, Sawyer R, Johnson SL. Confirmatory factor analysis of the Child Feeding Questionnaire: a measure of parental attitudes, beliefs and practices about child feeding and obesity proneness. *Appetite* 2001;36(3):201–10. <https://doi.org/10.1006/appe.2001.0398>.
- [58] Navarro Contreras G, Lagunes I Reyes. Validación psicométrica de la adaptación mexicana del Child Feeding Questionnaire. *Acta Invest Psicol* 2016;6(1):2337–49. [https://doi.org/10.1016/S2007-4719\(16\)30054-0](https://doi.org/10.1016/S2007-4719(16)30054-0).
- [59] Van Strien T, Oosterveld P. The children's DEBQ for assessment of restrained, emotional, and external eating in 7- to 12-year-old children. *Int J Eat Disord* 2008; 41(1):72–81. <https://doi.org/10.1002/eat.20424>.
- [60] Baños RM, Cebolla A, Etchemendy E, Felipe S, Rasal P, Botella C. Validation of the Dutch eating behavior questionnaire for children (DEBQ-C) for use with Spanish children. *Nutr Hosp* 2011;26(4):890–8. <https://doi.org/10.1590/S0212-16112011000400032>.
- [61] Van Strien T, Frijters JE, Bergers GP, Defares PB. The Dutch eating behavior questionnaire (DEBQ) for assessment of restrained, emotional, and external eating behavior. *Int J Eat Disord* 1986;5(2):295–315. [https://doi.org/10.1002/1098-108X\(198602\)5:2<295::AID-EAT2260050209>3.0.CO;2-T](https://doi.org/10.1002/1098-108X(198602)5:2<295::AID-EAT2260050209>3.0.CO;2-T).
- [62] Cebolla A, Barrada JR, Van Strien T, Oliver E, Baños R. Validation of the Dutch eating behavior questionnaire (DEBQ) in a sample of Spanish women. *Appetite* 2014;73:58–64. <https://doi.org/10.1016/j.appet.2013.10.014>.
- [63] Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. *Med Sci Sports Exerc* 2011;43(2):357. <https://doi.org/10.1249/MSS.0b013e3181ed61a3>.
- [64] Martínez-Gómez D, Ruiz JR, Ortega FB, Veiga OL, Moliner-Urdiales D, Mauro B. & HELENA Study Group. Recommended levels of physical activity to avoid an excess of body fat in European adolescents: the HELENA Study. *Am J Prev Med* 2010;39 (3):203–11.
- [65] Hollingshead, AB. Four-factor index of social status. Yale University Department of Psychology; 1975.
- [66] De la Peña FR, Villavicencio LR, Palacio JD, Félix FJ, Larraguibel M, Viola L, et al. Validity and reliability of the kiddie schedule for affective disorders and schizophrenia present and lifetime version DSM-5 (K-SADS-PL-5) Spanish version. *BMC Psychiatry* 2018;18:193. <https://doi.org/10.1186/s12888-018-1773-0>.
- [67] J. Cohen Statistical power analysis for the behavioral science 1988 Routledge Nueva Jersey, NJ.
- [68] Freedman DS, Berenson GS. Tracking of BMI zscores for severe obesity. *Pediatrics* 2017;140:e20171072.
- [69] Hayes JF, Fowler LA, Balantekin KN, Saelens BE, Stein RI, Perri MG, et al. Children with severe obesity in family-based obesity treatment compared with other participants: conclusions depend on metrics. *Obesity* 2021;29(2):393–401. <https://doi.org/10.1002/oby.23071>.
- [70] Rydler JR, Kelly AS, Freedman DS. Metrics matter: toward consensus reporting of BMI and weight-related outcomes in paediatric obesity clinical trials. *Obesity* 2022;30(3):571–2.
- [71] Davison KK, Kitos N, Aftosmes-Tobio A, Ash T, Agaronov A, Sepulveda M, et al. The forgotten parent: Fathers' representation in family interventions to prevent childhood obesity. *Prev Med* 2018;111:170–6. <https://doi.org/10.1016/j.ypmed.2018.02.029>.
- [72] Morgan PJ, Young MD, Lloyd AB, Wang ML, Eather N, Miller A, et al. Involvement of fathers in pediatric obesity treatment and prevention trials: a systematic review. *Pediatrics* 2017;139(2). <https://doi.org/10.1542/peds.2016-2635>.