“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”

Informed Consent Form (ICF)

Date of the document: 31/01/2017

INFORMATION SHEET AND INFORMED CONSENT: PARENTS / CAREGIVERS OF CHILDREN WITH OBESITY OR OVERWEIGHT

You and your child have been invited to participate in a research study. Before deciding whether to participate or not, it is important that they understand why this study is being conducted. Please take your time to carefully read the following information and consult it, if you wish. If you have any questions or if you would like more information, please contact us.

What is the objective of the present study? The general objective of this study is to examine the effectiveness of an intervention program in childhood obesity called the "ENTREN-F Program". The program consists of 12 sessions with a beweekly periodicity and an approximate duration of 6 months in which participating children will receive information about the factors involved in obesity and resources to modify lifestyle habits, as well as strategies to regulate their emotions. Different tasks and dynamics will be carried out to help them understand this pathology. In parallel, there will be an intervention of 8 sessions with the parents of the children who participate. In these parent sessions you will obtain resources to modify lifestyle habits, values and develop a healthy lifestyle.

To know if the program has been effective, all the participants of ENTREN-F Program will be followed up at post-intervention, 6, 12 and 18 months after intervention. The results will be compared with those obtained by two other groups that will carry out the same evaluation:
a) The intervention of the ENTREN-F (group with child intervention + family intervention)
b) With a group with intervention in the "ENTREN program" (without family intervention)
c) With a control group that will not participate in any of the programs of this research and that will carry out the usual treatment in the different Services of Endocrinology, Growth and Metabolism (modification of health behaviours).

The **specific objectives** of the study are to produce changes in:
- Weight and body contour.
- Habits of life (increase in physical activity, healthy eating habits)
- Psychological well-being (anxiety, depression, self-esteem)
- Emotional regulation, expression and abilities
- Family factors (general health, family functioning ...)

These factors will be evaluated through the following examinations: clinical history, weight and height measurements, psychophysiological record, interviews and questionnaires.

What is the study procedure? In this study we intend to evaluate 240 children between 8-12 years diagnosed with childhood overweight / obesity and their families. There will be a pre-intervention evaluation of the participants and their families in the Hospital Psychiatry and Psychology Service with an approximate duration of 2 hours for:

- An initial interview in which sociodemographic data are collected as level of studies and current work, medical and psychiatric history (15 minutes).
- A psychological interview with the child in which he will be asked about the presence of symptoms of different childhood problems (60 minutes).
- A measurement of the weight and height of parents and children (10 minutes).
- A measurement of the electrodermal activity and facial electromyography. The child will be asked to watch videos of different emotional content evaluating changes in facial expression and sweating through sensors on the face and finger (20 minutes).

During the following week, you will be asked:

- Fill a battery of questionnaires about eating habits, physical activity, psychopathology, regulation of emotions and personality (40 minutes).
- Measure physical activity during the week through an accelerometer that will be placed on the waist of your child.

All those participants who have completed this evaluation will be randomly assigned to one of the three conditions of the research:
a) intervention in the ENTREN-F program (12 child sessions + 8 parent sessions).
b) intervention in the ENTREN program (12 child sessions + 2 families)
c) control group (without participation in the previous programs). The participants who have been assigned to the control group will continue with their usual treatment in the Endocrinology, Growth and Metabolism Service of the Niño Jesús Hospital.

Follow-up intervention: After 6 months of the initial evaluation, all participants, regardless of the group to which they have been assigned, will carry out a 1-hour evaluation: Complete the questionnaires, weight and height measurements and the psychophysiological record (electrodermal activity and facial electromyography). At 6 and 12 months after this last evaluation, all participants will be cited, regardless of the group to which they have been

assigned, in a 25-minute session in which they will be carried out: Some of the questionnaires, and the measurements of the weight and height.

What are the risks and benefits? No adverse effects or potential risks are expected. Sometimes you may have the inconvenience of having to return the evaluation questionnaires, so you will be provided with different alternatives. If you have any concerns about your or your child's participation in this study, I can discuss it with the study investigators. Families are expected to benefit from the intervention program by improving their life habits, self-confidence and daily interactions with family members. Confidentiality within the group will be established and agreed upon at the first meeting of each group. You may not get any benefit to your health or your child's health by participating in this study.

My son and I have to participate? It is up to you to decide whether you want to participate or not, it is completely voluntary. If you decide to participate, you will be given this information sheet to save and you will be asked to sign a Consent Form. If they decide to take part in the present investigation, they are still free to withdraw at any time and without prejudicing the care of their child. In this case, all the data that you and your child have provided, would also be removed from databases and files. If they decide not to participate, it will not imply any change in the quality of the health care they receive.

What are the costs of the study? The tests carried out during the study will not cause you any expense. You will not receive financial compensation for participating in this study.

Confidentiality: All information that you provide during the course of the investigation will be kept strictly confidential. The information will be encoded (identifying details such as name and address will be deleted) and only then will it be entered into the computer. Confidential information will only be accessible to authorized persons (that is, to the staff members employed in the project, doctors and psychologists). No participant will be mentioned in the results of the study. The data will be protected according to Organic Law 15/1999 on the Protection of Personal Data and Royal Decree 223/2004.

Who organizes this study? The study is being carried out by the Autonomous University of Madrid and the Psychiatry and Psychology Service of the Niño Jesús Hospital in Madrid. The main researcher at the University is Dr. Ana Rosa Sepúlveda. The principal investigator in the Psychiatric Service of the Niño Jesús Hospital is Dr. Montserrat Graell. If you want more information about this research, you can contact: Dr. Ana Rosa Sepúlveda. Autonomous University of Madrid. Tel: 91 497 5214; email: anarosa.sepulveda@uam.es.

INFORMED ASSET SHEET: CHILDREN FROM 8 TO 12 YEARS OLD

My name is__and I am part of a group of psychologists in which we are dedicated to study why there are children who have a weight over the recommended and find ways to get them to return to a healthy weight.

We are now carrying out this study to try to help these children through an intervention program. We have told hospital doctors to invite all children between 8 and 12 years of age who weigh more than what is recommended for their age, and that is why you are here today.

If you decide to participate in this study, we will do a series of tests. The tests will consist of: 1) Weigh and measure you, 2) Ask you questions about you, your family, your school, among others, 3) Put an accelerometer for a week that measures the physical activity you do and 4) Measure the reaction of your body when watching a series of videos.

Some of the children we evaluate will do the program with us and another part will continue with their treatment with their usual doctor. This allocation will be made by lottery. If you participate in the program, you will meet with us and with 10 other children of your age here in the hospital for 2 hours every 15 days. This program will last approximately 6 months. In those days, we will do different activities and games with the aim of learning to eat healthier, increase physical activity and better understand emotions. It is expected that participation in these groups will help you achieve a healthy weight, although there is no certainty that it will produce any benefit.

To know if the program works, we will do the same tests when it finishes in 6 months. Neither the tests nor the program is expected to have negative consequences for you. You will only participate in the program if you agree. To decide, you can take the time you want and ask any questions you have both to me and your parents. If you do not want to participate in this study, no one will be angry with you or scold you. Even if you say you want to participate and then change your mind, you can stop coming whenever you want.

We will not tell other people that you are in this study, and we will not share information about you to anyone who does not work in the study. Any information we collect about you will be associated with a code instead of your name and the members of the investigation will know what that code is.

If you have chosen to participate in this investigation fill in this paragraph:

"I know that I can choose to participate in the study or not do it. I know I can retire whenever I want. I have read this information and I understand it. The questions have

been answered and I know I can ask questions later if I have them. I understand that any change will be discussed with me. I agree to participate in the research study. "

Name of the PI: ANA ROSA SEPÚLVEDA

Please read this section carefully and, if you agree, sign and date the box prepared for it below.

- I have been given the details and known risks of the study procedures I can perform.
- I understand that I am free to agree or refuse to participate and that I may suspend my participation at any time without giving explanations and without affecting the follow- up of my treatment. I will keep all my rights to receive treatment.
- I agree that the data collected in the study be used for the purposes described, including the transfer of data and its processing with respect to the anonymity and confidentiality of my personal data.
- I agree to allow direct access to my medical documents to authorized persons.
- I agree that at the end of the study, the data will be kept encrypted. If you access, these data will be kept for future research studies related to the present, with the same responsible and place, for X years. These studies must be approved by an officially accredited Research Ethics Committee to be carried out.
- I have read and understood the information presented in this document. I have been given the opportunity to ask questions and all my questions have been answered.
- I have received a copy of: the patient information sheet (3 pages typed on one side only), the schedule of the intervention program (1 page typed on one side) and this informed consent document (1 page typed by one single face), signed and dated on page.

I FREELY ACCESS TO PARTICIPATE IN THIS STUDY.

To sign simultaneously, that is, on the same date, for all parties:

Name of participant:
Date:
Sign:
Name of principal caregiver (father, mather or
tutor) Date:
Sign:
Name of responsible
Psychologist: Date:
Sign: