

A summary of the practical weight-management project and how it might be applied or developed in the future.

Project title: Behavioural Therapy and Mediterranean Diet in the Treatment of Obesity. The Garaulet Method.

Behaviour therapy (BT) is based on the classical principles of “conditioning”, which indicate that eating is frequently associated with external events that are closely linked to ingestion. The use of behavioural techniques is intended to help the patient to identify those signals that trigger inappropriate behaviour, both as regards eating and physical exercise.

On the other hand, different Mediterranean-style diets have been shown as a safe strategy for the treatment of obesity, the metabolic syndrome, and for helping to reduce associated cardiovascular risk. Indeed, greater adherence to the Mediterranean diet has been associated with a lower prevalence of abdominal obesity, and recently it was proposed that the Mediterranean diet is particularly effective for glycemic control.

Applying “Mediterranean diet” recommendations, a method of behavioural therapy and nutritional education (termed the “Garaulet Method”) was developed in 1994; its effectiveness was first assessed in 1999 on a sample of 100 individuals, and again in 2009 on a much larger sample of 1400 subjects. The very similar results of these two studies, carried out with a difference of ten years, demonstrate that behavioural therapy associated with nutritional education, caloric intake reduction and a balanced nutrient distribution based on the “Mediterranean diet” is useful for weight reduction and for the improvement of a number of obesity-associated derangements. In these years we have treated more than 10.000 patients and different centres of nutrition have been opened in several regions of Spain such as Madrid, Valencia, La Mancha, Murcia and recently in Andalusia (a complete description of the weight management program is explained in the next sections). However, more research is needed to increase the effectiveness of the program. Additionally during all these years the research of nutrition has dramatically developed and there are new concepts that could be useful in the weight loss management.

In this regard, during the last two years (in 2009) we have started a new project in Garaulet in collaboration with the university of Murcia (Spain) and Tufts University (Boston, USA) that have been supported by the Government of Education Science and Research of Murcia, by the Spanish Government of Science and Innovation and by the US department of Agriculture research services. The main aims of this project were to a) increase the effectiveness of the Garaulet treatment, b) analyze the main causes of dropping out c) detect the main barriers to weight loss d) determine whether the incorporation of new nutrigenetic and/or chronobiological tools could be useful in the diagnosis and the treatment of our patients. As a consequence of this research we have obtained new and interesting results that have been published in several research journals of high impact.

In the next future, our main goal is to apply in the clinical practice all this new knowledge obtained from research. However we must be careful in introducing these new tools of diagnosis without distorting the Garaulet Method concept. In this regard, we firstly need to design a complete and useful protocol able to be applied in our centres of nutrition. For this purpose, and before introducing all these ideas, we need to a) continue in the study of nutrigenetics factors in order to select from the large range of polymorphisms studied those that could be useful to predict the success of the treatment; b) to design new tools in the psycho-behavioural characterization of the patients; c) select the best tool for the chronobiological characterization of the subject in the clinical practice. All this with the final purpose of personalizing the treatment based on a combination of genotyping, chronotype and psycho-behavioural characterization without forgetting the Mediterranean Diet principles. Once designed a final protocol our intention is to expand this actualized program to other regions in Spain and if possible to other European countries.

State-of-the-art

Obesity treatment has undergone numerous changes in recent decades. Up to the 1960s, hypocaloric diets were practically the only treatment recommended, while the 1970s saw the introduction of behavioural therapy, promoting a change in lifestyle and eating habits of the patient as an alternative therapy. Since then, many studies have underlined the importance of behavioural therapy in all forms of weight control, be they dietetic, pharmacological, exercise-based, or even involving morbid obesity surgery. However, in 1988 the American

Medical Society declared that behaviour therapy itself did not produce favourable results unless accompanied by dietetic treatment and increased exercise.

Behaviour therapy (BT) is based on the classical principles of “conditioning”, which indicate that eating is frequently associated with external events that are closely linked to ingestion. The use of behavioural techniques is intended to help the patient to identify those signals that trigger inappropriate behaviour, both as regards eating and physical exercise. It is also a question of the patient learning to develop new responses in the face of these signals, seeking positive reinforcement or reward when the correct behaviour is followed. This type of intervention has evolved from its beginnings and, alongside classical self-monitoring techniques and stimulus control, new techniques involving social support and increased physical exercise have been included. In the last twenty years, BT for obesity control has incorporated cognitive therapy techniques. The underlying principle is that our thoughts directly affect our emotions and, as a consequence, our acts. It is a question of changing our pessimistic thoughts, frequently associated with negative and sometimes self-destructive events, for others that lead to more suitable behaviour as far as eating is concerned. With cognitive therapy patients learn to establish realistic goals, both as regards weight and behaviour, and to evaluate their progress in modifying eating and exercising habits. The aim is also to correct the negative effects that are produced when objectives are not achieved, basing treatment on techniques previously developed for depression, anxiety and bulimia nervosa.

Despite the many widely attested benefits associated with weight loss, the usefulness of dietetic treatment is questioned by some sectors of the scientific and medical community, since some studies have shown that as many as 80% patients abandon treatments before achieving their goal; within a year they will have regained 30-50% of the weight lost and after four years their weight will have stabilised at 4% below the initial weight. The situation has nonetheless improved substantially in the recent years, due largely to the increased length of behavioural therapies. However, the success of weight loss treatment depends on the structure, principles, and techniques used with the patient. More studies are needed to improve obesity therapy outcomes.

Evidence points toward a possible role for the Mediterranean diet in preventing overweight/obesity. Although there is no “all-inclusive” diet for the treatment of obesity and metabolic syndrome, a Mediterranean-style diet has most of the desired attributes, including lower refined carbohydrate content, high fiber content, moderate fat content (mostly unsaturated), and moderate to high vegetable protein content.

Different Mediterranean-style diets have been shown as a safe strategy for the treatment of obesity, the metabolic syndrome, and for helping to reduce associated cardiovascular risk. Indeed, greater adherence to the Mediterranean diet has been associated with a lower prevalence of abdominal obesity, and recently it was proposed that the Mediterranean diet is particularly effective for glycemic control. Moreover, results suggest that promoting eating habits consistent with Mediterranean diet patterns may be a useful part of efforts to combat obesity. Nevertheless, more research is needed to substantiate these statements.

In this regard, during the last two years we have intensified our research in the effectiveness of the treatment and we have started a new line of research in order to decide whether the incorporation of new nutrigenetic and/or chronobiological tools could be useful to personalized health care and nutrition based on a combination of genotyping and psycho-behavioural characterization.

THE GARAULET METHOD

Applying “Mediterranean diet” recommendations, a method of behavioural therapy and nutritional education (termed the “Garaulet Method”) was developed in 1994; its effectiveness was first assessed in 1999 on a sample of 100 individuals, and again in 2009 on a much larger sample of 1400 subjects. The very similar results of these two studies, carried out with a difference of ten years, suggest that behavioural therapy associated to alimentary habit control, caloric intake reduction and a balanced nutrient distribution based on the “Mediterranean diet” is useful for weight reduction and for the improvement of a number of obesity-associated derangements. More than 10,000 patients have been treated during those years and in the current moment we have 14 different Centres of Nutrition in several regions of Spain such as Madrid, Valencia, Murcia, Albacete, etc. And we are just starting the constructions for Andalusia. For additional information please see www.garaulet.com

Since 2009 a new project have been started in order to give a scientific support to this methodology. This project has been performed in collaboration with the University of Murcia (Spain) and Tufts University (Boston,

USA) that have been supported by the Government of Education Science and Research of Murcia, by the Spanish Government of Science and Innovation and by the US department of Agriculture research services.



Figure 1: Centres of Nutrition Garaulet in Spain

1. Health professionals in Garaulet

Our system is a franchise. Different nutritionist interested in developing the Garaulet Method in new regions, are trained in our main office during 6 months until we consider that they are ready to manage their own centre. A Known How has been developed, and everything is described, including every step required to apply this method .i.e. group therapy, how to assess the patient's clinical history, anthropometric techniques, 24h recall methods to assess dietary intake, etc. (see supplemental data in Spanish). The structure is directed by Vital Garaulet (director of Franchise), Marta Garaulet (Director of Research) and Teresa Hernández (Director of Training). In each Centre of Nutrition the staff is composed by two persons, the main nutritionist, and the dietician. In the following figures we include an image of the total staff integrated in Garaulet (Image 1) and the description of personnel in the current moment (Figure 1).



Image 1. Garaulet Staff

Characteristics of the health professionals in Garaulet

In Garaulet we are aware that in general health professionals are usually reticent about the use of behavioural therapy to treat obesity, and tend to underestimate the effects of suitable education on lifestyle habits. However, it is important for the sector to realise that BT is easy to standardise and can be easily applied in clinical practice. To help patients to help themselves, health professionals need to have suitable techniques at their disposal. The process may consist of different levels of preparation such as guidance, communication,

nutritional education, eating habits and behavioural techniques and these factors are considered in Garaulet for the selection and further training of our therapists. Four requirements have been described for the patients' behaviour to be changed: motivation, knowledge, techniques and support. The principal characteristics of the therapist must be the unconditional acceptance of the patients as they are, to be natural and to show empathy.

Treating obesity is clearly not easy and the results are often worse than expected. It can even affect the self-esteem of the professional, especially after a long time being engaged in the activity. In this case, it will be of use to look at the relevant scientific literature and see whether the results obtained are similar. If feelings of frustration are evident, they are best shared with colleagues and, more than anything, ineffective therapy should not be applied. In this regard the organization of Garaulet Nutrition. S.L. is very useful to share information among therapists and support.

The following of guidelines are considered in Garaulet to help patients in the clinics:

1. Teach *why*. The professional must be clear with the patient and explain the reasons for the treatment. Patients are adult people who need to feel interested in the therapy techniques.
2. Decide *what*. Specific goals must be established in the short-term, helping the patient to select the objectives and to design a weight loss plan.
3. Define *how*. It is important to identify barriers to weight loss and the tools to achieve it.
4. Avoid criticism to the patient. Body weight control is difficult, and questioning the patient's motivation is of no use.
5. Have patience.
6. Help the patient to maintain their self-esteem throughout the treatment.
7. Be realistic about weight loss expectations. Avoid hardly attainable goals.
8. Focus on the importance of the changes in the patient's habits, rather than on the quantity of the weight lost.
9. Stress the advantages and success that are not related to weight loss, such as improvement of agility, quality of life, reductions in serum lipids, control of blood glucose, diminution of blood pressure, etc.
10. The patient must feel comfortable to return to the treatment after relapses. Sometimes, the patient quits the therapy because they feel guilty or afraid of having disappointed the therapist.

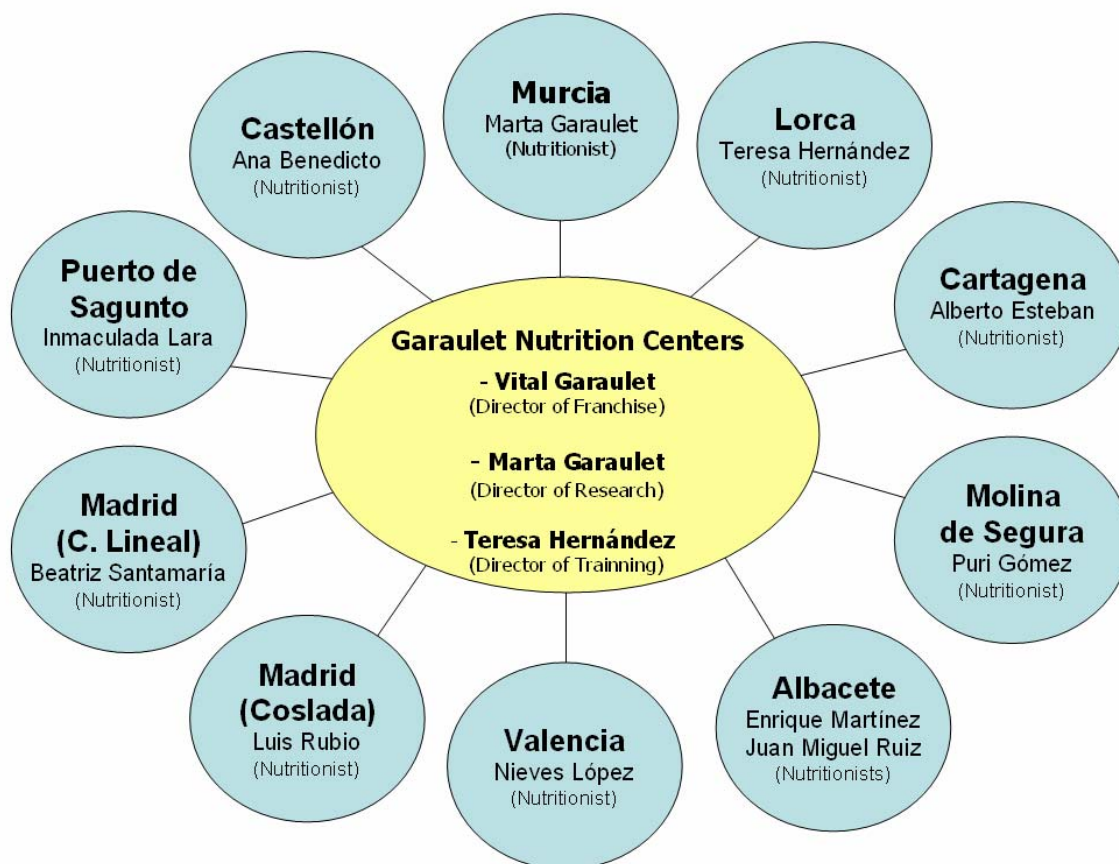


Figure 2. Description of the health professionals in Garaulet in the current moment

2- The patients:

During these years more than 10.00 patients have been treated in Garaulet. The 80% of the subjects are overweight or obese, (60% women, 20% men) and 20% of the subjects come to Garaulet to learn how to eat appropriately following the Mediterranean Diet principles. Of note, 10% are children and they attend weekly to special groups designed for children, with the attendance of the parents every two weeks.

Image 1: Childen Group Therapy in Garaulet



Characteristics of the patients before and after the treatment.

Characteristics of the population before and after the dietary behavioural treatment are shown in the next table. Our results from a study performed in 1400 subjects attending to a Garaulet Center of Nutrition indicate that all the anthropometric variables were significantly improved after treatment. Serum levels of glucose, total cholesterol, uric acid, and blood pressure were also significantly reduced.

The mean duration of treatment was 34 wk, including the maintenance phase. The average weight loss was 7.8 kg. The percentage of weight loss when compared with the initial body weight was 9.7, the percentage of body fat loss was 4.6, and the rate of weight loss was 650 g (Table 3). Effectiveness of treatment was affected by the grade of obesity.

Table 2. Characteristics of the population studied before and after following the behavioral treatment.

Measures	Total group Before treatment (N=1406)	Total group After treatment (N=1406)	P
Weight (Kg)	82.70 ± 16.14	77.20 ± 15.29	0.0001
BMI (Kg/m ²)	30.50 ± 5.36	28.50 ± 5.13	0.0001
Body fat (%)	37.30 ± 6.38	33.60 ± 7.51	0.0001
Hip (cm)	114.00 ± 9.00	108.00 ± 9.00	0.0001
Waist (cm)	103.00 ± 13.00	96.00 ± 13.00	0.0001
WHR	0.91 ± 0.08	0.89 ± 0.08	0.0001
Glucose (mmol/L)	5.56 ± 0.96	5.18 ± 0.63	0.0001
Cholesterol (mmol/L)	5.25 ± 1.00	4.68 ± 0.88	0.0001
Uric acid (mg/dl)	5.10 ± 1.74	4.70 ± 1.50	0.0001
Haemoglobin (g/L)	143.00 - 16.90	141.00 - 17.10	0.353
Diastolic pressure (mmHg)	7.50 ± 1.10	6.93 ± 0.14	0.0001
Systolic pressure (mmHg)	12.00 ± 1.00	11.00 ± 2.00	0.0001

Patients with grade II obesity (BMI 30–34.9 kg/m²) achieved the best results. No significant differences were found between genders in the rate of weight loss, except for week 6 of treatment (men 0.825 kg, women 0.600 kg; $P < 0.001$). When comparing those patients who dropped out of treatment ($n = 92$) with those who finished ($n = 1310$), significant differences in weight loss in weeks 5 (0.495 kg versus 0.630 kg), (0.446 kg versus 0.643 kg), and 7 (0.380 kg versus 0.555 kg) were observed between those who dropped out and those completing the program, respectively.

89% of the subjects achieved all the Mediterranean recommendations, whereas 11% did not attain the diet recommendation distribution of the principal components. The total percentage of attrition of those who agreed to participate fluctuated from 4% to 9% depending on seasonal variation, with the highest percentage during Easter, summer, and at Christmas. The main causes for dropping out were as follows: stress (37%), vacations and holidays (15%), illness or pregnancy (8%), did not want to measure food portions (6%), psychological causes (4%), incompatibility with schedule (3%), social pressures (2%), and failure to understand diet (1%). The remaining 18% reported other causes.

DESCRIPTION OF THE HEALTH PROFESSIONAL ACTIVITIES IN GARAULET

1-Dietetic intervention in Garaulet Method: The Mediterranean Diet in behavioural therapy

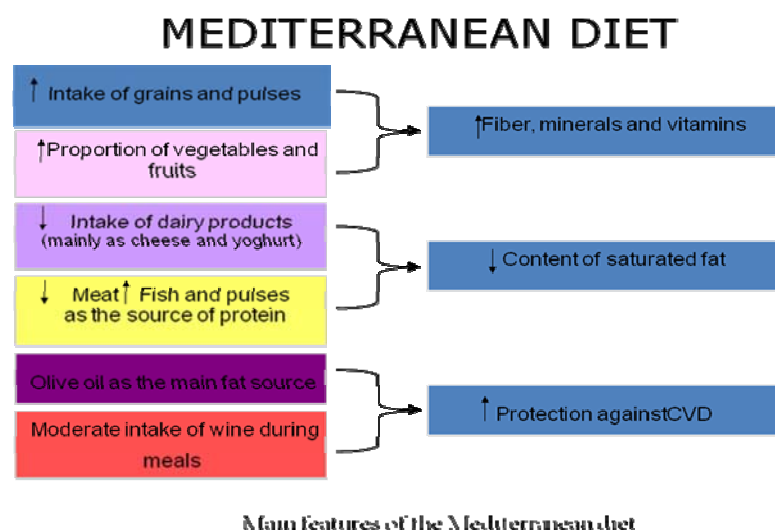
Different Mediterranean lifestyle programmes performed in Mediterranean and non-Mediterranean countries have shown that BT accompanied by food habit control, caloric reduction and a balanced nutrient distribution based on the Mediterranean diet is useful for losing weight and for improving obesity-associated alterations. An interesting finding from a randomized controlled clinical trial was that a moderate fat, energy-controlled Mediterranean-style diet offered an alternative to a low-fat diet, with higher adherence and consequently improvement in weight loss.

Indeed, a greater adherence to the Mediterranean diet has been associated with lower prevalence of abdominal obesity, and it has been also proposed that the Mediterranean Diet is particularly effective on glycaemia control.

1.1-Characteristics of the Mediterranean diet

The principles of the Mediterranean diet are summarized in figure 3. The application of the Mediterranean diet for weight loss purposes must be accompanied by reduced energy intake (reductions of 500-1,000 kcal/day); fat must not exceed 30% energy, and oleic acid must constitute at least 55% total fat at the expense of saturated fats –this can be attained by using olive oil as culinary fat. It is important to bear in mind that the ingestion of fat has been shown to be a main factor in obesity. In this regard, recent nutritional recommendations from Greece based on the Mediterranean pyramid were criticised, because fat intake has been increasing in this country since the 1950's due to the ingestion of olive oil, leading to a substantial overall weight gain. Another important consideration is that a hypocaloric diet (1,200-1,800 kcal) with a considerable contribution of vegetal products (lentils, chickpeas, beans) to total proteins must be varied, and care must be taken to provide sufficient consumption of haemo iron. Doing so, iron-related haematological parameters will be maintained within normal values.

Figure 3. Features of the Mediterranean Diet



1.1-1. Advantages of the Mediterranean diet in behavioural treatment of obesity

The main advantages of the Mediterranean diet in the treatment of obesity are consequence of its characteristics are the following:

- It is highly satiating, due to high fibre intake.
- It is composed of high-volume foods with low calorie density.
- Given its high carbohydrate content, it does not trigger specific hunger and therefore binge-eating.
- For the same reason, it is not ketogenic.
- Even though it can be hypocaloric, it keeps adequate nutrient proportions.

1.2-Particular Dietary recommendations in Garaulet Method

Diets that do not ensure recommended nutrient intake, *i.e.* 10-15% protein, 30-35% fat and 50-60% carbohydrates are not suitable for BT. The idea is to educate the patient to assume correct eating habits that will last a lifetime. Our health professionals have the obligation to keep abreast of all the myths and errors that different diets give rise to, and to transmit to the patient recommendations based on established nutritional knowledge. In general, diets used in BT are hypocaloric, with energy contents of at least 1,200 kcal, in which the recommended nutrient proportions are maintained, with ≥ 0.8 g protein/kg body weight/day and ≥ 100 g carbohydrates/day to avoid ketogenesis. Moreover, healthy habits such as adequate breakfast, not missing meals (3-5/day), eating slowly, moderate portions size, etc., are all part of the therapy (Table 1).

Table 1. Main dietary characteristics in Garaulet

- **Reduction in energy intake** (reductions of **500 to 1000 kcal/day**), of which fat must not exceed 30%, while oleic acid must constitute at least 55%
- The idea is **to educate the patient** to assume correct eating habits that will last a lifetime but without losing **the pleasure of eating**
- **Restrictions should not be too rigid**: flexibility in the diet is associated with less **craving** and fewer **binge-eating**, and greater success in **maintaining** lost weight
- Occasional treat, such as cakes, alcohol (wine), sweets, etc., which should be enjoyed with no feeling of guilt. (**Optional calories**)

In the Garaulet Treatment the individual energy requirements are calculated using the Harris-Benedict formula and then, based on the type and level of physical activity, were decreased to about 2.6 MJ/day so as to induce a weight loss of approximately 0.5 to 1.0 kg/week.

The diet used is of the Mediterranean type, with the macronutrient distribution following the recommendations of the Sociedad Española de Nutrición Comunitaria (Spanish Society of Community Nutrition): 35% of the total energy from fat (<10% saturated and 20% monounsaturated fats), 50% from carbohydrates, and 15 to 20% from proteins. The subjects are advised to consume unrestricted amounts of vegetables (at least 200 g/day) and fruits (at least 250 to 300 g/day) and to use olive oil as the only cooking fat.

They are also encouraged to include the following in their midday lunches: at least 100g legumes thrice weekly, 100 g rice once weekly, 100 g wheat and pasta once weekly, and fish at least once weekly. The daily intake recommendations for cholesterol and fibre are <300 mg and >15 g, respectively. The subjects are also motivated and rewarded with extra calories (optional calories) and extra food exchanges ("floating portions") for special occasions.

Image 2. Therapist showing the “Self-Monitoring” notebook to a patient.



Patients are encouraged to design their own menus, after giving them the number of interchanges that they need to consume in every food group. An established daily menu is not given in order to help the patient to learn to design their own diet considering their particular and individual characteristic of life, dietary habits and family and work conditions. Consequently, to every subject one “self-control” dietary notebook is given and they are encouraged to write everyday everything they eat, and also to point out the number of interchanges or portions.

2. Treatment structure

The structure of the treatment (the “Garaulet Method”) has been described elsewhere and is illustrated in Figure 4. During the first four months the subjects, in groups of ten each, attend once-weekly, 60-minute therapy sessions; this period is followed by a five-month maintenance period. During the latter, meetings are held initially every two weeks and then at monthly intervals. The sessions are conducted by the nutritionist.

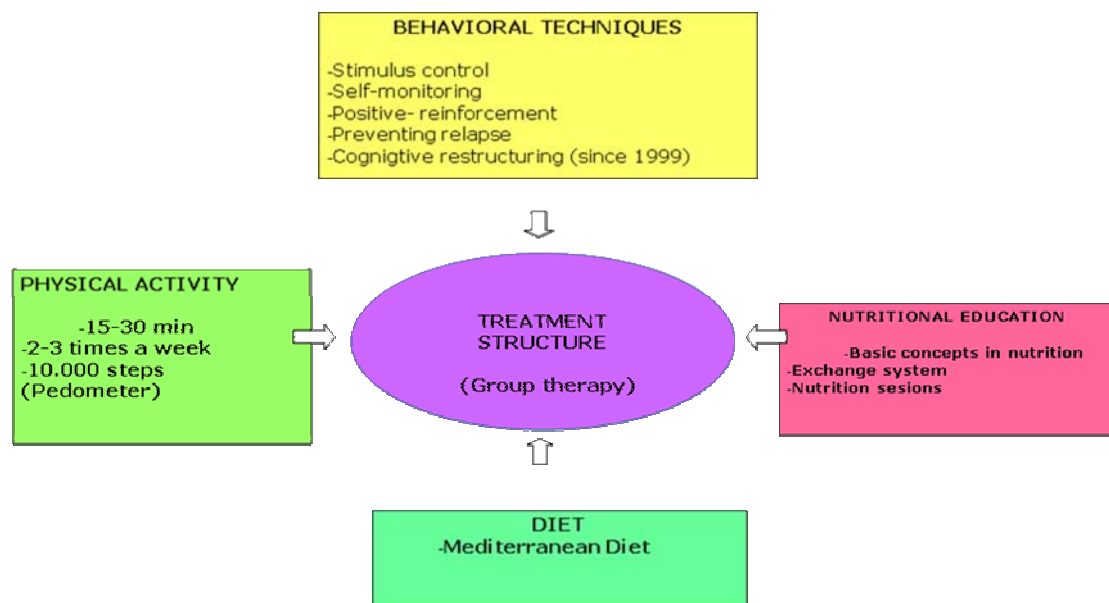


Figure 4. structure of the treatment

2.1. Nutritional education

This is given in order to help the subjects plan their own menus, and also to induce and train them to adopt appropriate lifestyle and eating habits. Theoretically, losing weight through the diet should be easy, since it consists of producing an energy deficit in which energy intake is less than energy expenditure. However, dieticians know how difficult it is to instil correct eating habits in modern day society, where it is so easy to obtain tasty, high-calorie food and where any celebration is an excuse for over-eating.

From a BT point of view, it is important to bear in mind the principle behind this type of therapy —changing a patient's habits, especially with a view to long-term change. In this sense, not all diets are useful for BT even if they have demonstrated their usefulness for reducing weight. The idea is to educate the patient to assume correct eating habits that will last a lifetime. Our health professional has the obligation to keep abreast of all the myths and errors that different diets give rise to, and to transmit to the patient recommendations based on established nutritional knowledge.

2.2. Behavioural techniques

These included stimulus control, self-monitoring and reinforcement. From 1999 onwards, new and additional cognitive behavioural therapy strategies have been added to the original Garaulet programme, such as cognitive restructuring to help the subjects learn to recognize and modify weight-related thoughts or beliefs, so as to revise less-helpful attitudes (such as for instance the “all-or-nothing” one).

Other such techniques included stress confrontation, social support and controlling the food intake speed. Beyond group therapy, one obligatory individual session with the therapist every five weeks has been included in the new version of the programme. New auxiliary tools have also been incorporated to sustain and buttress these behavioural techniques, such as the use of a pedometer and/or an oil sprayer, a new book on positive reinforcement, and a recipe book based on the Mediterranean lifestyle.

2.2-1. Behavioural Techniques used in Garaulet

- Stimulus control: this refers to how our immediate environment can be altered to promote behaviour that will help the patient to lose weight. For example, restricting the number of places where eating is permitted, eating slowly, not missing meals, keeping palatable food in opaque containers, etc.
- Self-monitoring: this is considered one of the principal pillars of BT and refers to keeping a daily log of food consumed and exercise taken. The aim is to increase the patient's awareness of what they eat and of possible situations of risk that may influence eating habits. By means of this daily log, the patient may learn, for example, at what time they usually eat, that they eat when stressed, depressed, bored, or in the company of certain people, etc. (table 2).
- Positive reinforcement: with incentives not related with food, such as new clothes when a given objective is attained, or small gifts, prizes or diplomas when the aimed weight is reached.
- Cognitive restructuring: by this means, patients learn to recognise and modify weight-related thoughts or beliefs. This is an attempt to revise thoughts of self defeat and attitudes such as “all or nothing”. This technique helps patients with low self-esteem, by substituting negative and self-destructive thoughts by positive and stimulating ones.
- Preventing relapses: by teaching how to identify “slips” and which techniques can be applied to avoid them.

Other techniques include stress confrontation, social support (friends and family), problem resolving, controlling the speed of eating, etc.

Image 2. A special notebook for self-monitoring in children



One example of daily self-monitoring notebook . Garaulet (2004)*

Day Monday 23 January					
Hour	Food and drink consumed	Place		Portions Optional calories	Comments
9:00AM	1 glass milk + sugar 1 toast with ham 1 orange juice	Bar	*	1Ma, 1B, 1P, 2F, 20 kcal	Toast weighed approx. 60g, though I did not weigh it.
3:00 PM	1 salad + oil 1 plateful lentils + rice	Home (dining-room)	*	2V, 1B, 1P, 1Fat, 2F	I did it great, I felt satisfied.
	1 cup fruit salad	Home (bedroom)	*	150 kcal	I was bored reading in my bedroom
	1 portion chocolate	Home		1B, 2P, 1M, 1F	I felt completely satisfied
	Sandwich cheese + ham				
7:00 PM	1 low-fat yoghurt + cookies				
10.00 PM	1 banana				

Note: You should write down your intakes as soon as possible. Put an asterisk in column 4 when you think you have eaten or drunk too much; use your own point of view and no one else's. a (initials preceded by a number indicate the standardised portions consumed from each group of food: M: milk; B: bread and cereals; P: protein (meat, fish, eggs, etc.); F: fruit; V: vegetables.

*Garaulet M. Pierde peso sin perder la cabeza. Madrid. Ed. Editec. 2004. (In Spanish)

2.3. Group therapy

In Garaulet, behavioural therapy is usually carried out in groups of ten to twenty people in sessions lasting 60-90 minutes led by the nutricionist. This is completed by an individual interview every 5 weeks of treatment. In our centres of nutrition, after six months of treatment, group treatment produced greater weight loss than individual therapy (figure 5), probably because of the empathy generated in a group situation, the social support offered, and a healthy dose of competitiveness, all of which helped to produce a change in lifestyle.

These results are in agreement with those found in a Mediterranean Population from Spain (Garaulet Method). It is important to highlight that In Garaulet in the last years the group attendance has increased from 60% in 1999 of the total subjects to the 90% in 2009, a situation that has been crucial for the increase in the effectiveness of the treatment.

The choice of topics in group work is of crucial importance and will differ between therapies. Cooper and co-workers, for instance, used topics such as “recording what you eat”, “energy balance”, “social eating”, “preparing for the holiday”, or “special occasions”. In Garaulet Method the talks included in the treatment can be classified into four types:

- Nutrition-based sessions, to provide ideas to help in selecting foodstuffs and maintaining the dietary record;
- Physiology-based sessions, to help explain why the body puts on weight, the processes of nutrient absorption and digestion, and the physiology of weight loss;
- Behavioural and cognitive sessions, to help the subjects in controlling stimuli, avoid negative thoughts and detect –and eventually circumvent– the main obstacles and barriers to weight loss;
- Practical ideas sessions, to help the subjects understand the importance of breakfast and to organize outings, shopping lists, recipes, menus, etc. One simple recipe was described and explained at each weekly session.



Figure 5. One example of group therapy in Garaulet (Cartagena/Murcia)

2.4. Physical exercise in behavioural therapy

Physical exercise is a key component in treating obesity, since it can help to increase energy expenditure, diminish food intake, increase self-esteem and overcome depression. Even so, some studies have shown that contribution of exercise to weight loss is slight; for example, it would be necessary to walk 60 km to metabolise

1 kg of body fat. Certainly, the effect of exercise on weight loss varies, and while most studies demonstrate small decreases in weight of approximately 2 kg, others point to no benefit at all. When the weight loss achieved by behavioural treatments involving either physical exercise or changes in eating habits were compared, the former was seen to be less successful. However, exercise is clearly beneficial for the well being of the obese individual, since it increases the maximal oxygen uptake (VO_2 (max)) and therefore cardiorespiratory health.

Several studies have shown that exercise can be a useful tool for maintaining long-term healthy weight loss. Unfortunately, in clinical practice most programmes based on exercise raise false expectations in patients, which lead to exercise being abandoned. In BT, one of the main concerns in recommending exercise is to establish programmes suited to the individual, and most importantly to set attainable goals. The reduction of sedentary habits —of which watching television is the paradigm— is important in the treatment of obesity. Behavioural studies have shown that the reduction of sedentary habits is as important for losing weight as taking specific exercise.

In Garaulet the use of a pedometer (figure 6) is an incentive to reach 10,000 paces per day is a practical help in this respect. Activity logs, too, are useful for recording the degree of inactivity that is, the number of hours spent sitting or lying, the activities that form part of the daily life of patients, and the time dedicated to specific exercise. Cooper and co-workers, in their BT programme, classified physical activity into three categories and provided a series of recommendations concerning each (figure 6).

Exercise

Summary of daily activity of a BT patient.

- Inactivity (hours): 8 hours in bed, 3 hours sitting
- Daily activity (paces): 3.860 paces
- Specific exercise (minutes o type): Tennis (1 hour)

- Adapted from Cooper et al., 2003

10,000 paces a day



Dra. Marta Garaulet Aza

Figure 6. One example of Activity logs and an image of the pedometer in Garaulet

Practical recommendations in Physical activity Garaulet

To emphasize individual goals of 15 to 30 or more minutes of moderate-intensity physical activity a least 2 or 3 times weekly unless a medical contraindication existed. The subjects were encouraged to use pedometer in order to achieve a goal of at least 10,000 steps' daily walk.

RESEARCH IN GARAULET

Although the Garaulet program has demonstrated to be useful in the clinical practice in Obesity we are aware that more research is needed to increase the effectiveness of the program. Additionally during all these years the research of nutrition has dramatically developed and there are new concepts that could be useful in the weight loss management.

In this regard, during the last two years (in 2009) we have started a new project in Garaulet in collaboration with the University of Murcia (Spain) and Tufts University (Boston, USA) that have been supported by the Government of Education Science and Research of Murcia, by the Spanish Government of Science and Innovation and by the US department of Agriculture research services.

Objectives in the last two years

The main aims of this project were the following:

1. Assess the effectiveness of a dietary behavioural and nutritional education program based on the principles of the Mediterranean diet (Garaulet Method) for treatment of overweight and obesity, considering the following aspects: average weight and percentage of body fat loss; changes in body fat distribution, in biochemical variables, and in blood pressure; ability to meet Mediterranean diet recommendations; mean duration of treatment; and percentage of attrition.
2. Analyze the main causes of dropping out
3. Detect the main barriers to weight loss occurring in this Mediterranean population
4. Determine whether the incorporation of new nutrigenetic and/or chronobiological tools could be useful in the diagnosis and the treatment of our patients.

Results

As a consequence of this research we have obtained new and interesting results that have been published in several research journals of high impact.

Objective 1. Methods: A total of 1406 obese subjects (body mass index, 3165 kg/m²), aged 20–65 y, from a Mediterranean area in southeast Spain were subjected to a weight-reduction program. To evaluate effectiveness, weight loss, body fat distribution, biochemical variables, blood pressure changes, mean duration of treatment, percentage of attrition, and the ability to fulfil a Mediterranean diet pattern were assessed. **Results:** The behavioural therapy program was effective for the treatment of obesity. The average weight loss was 7.7 kg. The duration of treatment was 34 wk. Eighty-nine percent of subjects fulfilled the Mediterranean principles during the program, and all the variables studied were significantly improved. Attrition was 4–9%, with the main reason being stress (37%). **Conclusions:** Dietary/behavioural treatment based on Mediterranean dietary principles is effective in clinical practice. Nutrition professionals should encourage their patients to record food intake and to attend group therapy.



Main article:

Corbalán MD, Morales EM, Canteras M, Espallardo A, Hernández T, Garaulet M. Effectiveness of cognitive-behavioural therapy based on the Mediterranean diet for the treatment of obesity. *Nutrition*. 2009 Jul-Aug;25(7-8):861-9.

Objective 2 and 3. In the course of attempting to lose weight, most patients will encounter a number of obstacles and barriers, some of these major ones. Identification of such obstacles might be crucial for assessing whether they are curtailing the patient's progress and the eventual therapeutic success. An assessment of these barriers has already been carried out in a North European population. Our aim has been to validate the questionnaire used in that assessment for a Spanish Mediterranean population undergoing dietary-behavioural therapy for losing weight, and thus to identify the main obstacles to weight loss in this particular population. To determine the main barriers to losing weight, a "Barriers to Weight Loss" checklist was completed. Our results show that main obstacles to weight loss were "losing motivation," being "prone to stress-related eating," and being liable to eat when bored. Recording food intake and assisting group therapy were also important tools for losing weight ($P<0.05$).

Main article:

Garaulet M, Pérez de Heredia F. Behavioural therapy in the treatment of obesity (I): new directions for clinical practice. *Nutr Hosp*. 2009 Nov-Dec; 24(6):629-39.

Attrition

1999 Jeffrey et al (1)	1999 Garaulet (<i>J Hum Nutr</i>)	2008 Garaulet (<i>Nutrition</i>)
80%	59%	4-9%

Objective 4. in this regard we have done a epidemiological approach: to assess, in a large population (n=2000) if different Single Nucleotide Polymorphisms (SNPs) could be related to obesity and weight loss and whether they are modulated by external factors, such as sleep and diet (Nutrigenetic studies with DNA isolation and clock genotyping); we have also performed a clinical approach: to select a subsample population (n=300) divided in carriers and non-carriers of the SNP and investigate the behavioural (sleep quality and duration, eating patterns and chronobiological characteristics) and hormonal factors which could explain the previously reported association between SNPs and weight loss.

Nutrigenetics: Our results showed that several *CLOCK* polymorphisms may predict outcome of body weight reduction strategies based on low-energy diets. Carriers of the C allele may have more obesity and a higher difficulty in losing weight in response to a low-energy diet. The difficulty was consistently observed through-out the whole treatment, although this was more evident since the third month of treatment.

On the other hand, we deduced from our research that other clock gene "Period 2" (PER2) is implicated in attrition in a weight loss treatment and may modulate eating behaviour-related phenotypes in obese patients, supporting a regulatory role of this genetic variant on eating behaviour. The identification of *PER2* genetic variants can be useful to detect participants more prone to dropping out and to personalize

behavioural and cognitive techniques in the treatment of obesity towards a more effective treatment. Other polymorphisms of FTO, PPAR-gamma, ApoA5, ApoA2 and Sirtuin have been also related to weight loss.

Chronobiology: Findings indicate differences in melatonin and cortisol circadian patterns between obese and normal-weight women. Diminished daily amplitude was associated to abdominal fat and obesity-related metabolic disturbances in blood pressure, glucose and plasma lipids regulation, ghrelin and adipocyte-secreted hormones such as leptin and adiponectin. Moreover, obese women displayed a less defined Wrist Temperature circadian rhythm, with a more flattened pattern, particularly during early morning and in postprandial time. These results could be indicative of a lower ability to synchronize with external inputs, or to a more irregular sleep and food patterns. These findings could represent a step towards personalized health care and nutrition based on a combination of genotyping and chronobiological characterization.

Main articles:

- Garaulet M, Sánchez-Moreno C, Smith CE, Lee YC, Nicolás F, Ordovás JM. Ghrelin, sleep reduction and evening preference: relationships to CLOCK 3111 T/C SNP and weight loss. PLoS One. 2011 Feb 28;6(2):e17435.
- Smith CE, Ordovás JM, Sánchez-Moreno C, Lee YC, Garaulet M. Apolipoprotein A-II polymorphism: relationships to behavioural and hormonal mediators of obesity. Int J Obes (Lond). 2011 Mar 8. [Epub ahead of print]
- Sánchez-Moreno C, Ordovás JM, Smith CE, Baraza JC, Lee YC, Garaulet M. APOA5 gene variation interacts with dietary fat intake to modulate obesity and circulating triglycerides in a Mediterranean population. J Nutr. 2011 Mar;141(3):380-5. Epub 2011 Jan 5.
- Garaulet M, Ortega FB, Ruiz JR, Rey-López JP, Béghin L, Manios Y, Cuenca-García M, Plada M, Diethelm K, Kafatos A, Molnár D, Al-Tahan J, Moreno LA. Short sleep duration is associated with increased obesity markers in European adolescents: effect of physical activity and dietary habits. The HELENA study. Int J Obes (Lond). 2011 Jul 26. doi: 10.1038/ijo.2011.149. [Epub ahead of print]
- Corbalán-Tutau MD, Madrid JA, Ordovás JM, Smith CE, Nicolás F, Garaulet M. Differences in daily rhythms of wrist temperature between obese and normal-weight women: associations with metabolic syndrome features. Chronobiol Int. 2011 May;28(5):425-33.

Representative peer-reviewed publications in the last two years, related to weight management

- 1-Gómez-Santos C, Larqué E, Granero E, Hernández-Morante JJ, Garaulet M. Dehydroepiandrosterone-sulphate replacement improves the human plasma fatty acid profile in plasma of obese women. Steroids. 2011 Jul 27. [Epub ahead of print]
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- 3-Corbalán-Tutau MD, Madrid JA, Ordovás JM, Smith CE, Nicolás F, Garaulet M. Differences in daily rhythms of wrist temperature between obese and normal-weight women: associations with metabolic syndrome features. Chronobiol Int. 2011 May;28(5):425-33.
- 4-Garaulet M, Ordovás JM, Gómez-Abellán P, Martínez JA, Madrid JA. An approximation to the temporal order in endogenous circadian rhythms of genes implicated in human adipose tissue metabolism. J Cell Physiol. 2011 Aug;226(8):2075-80. doi: 10.1002/jcp.22531.
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- 6-Garaulet M, Sánchez-Moreno C, Smith CE, Lee YC, Nicolás F, Ordovás JM. Ghrelin, sleep reduction and evening preference: relationships to CLOCK 3111 T/C SNP and weight loss. PLoS One. 2011 Feb 28;6(2):e17435.

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